S-Monovette® Lithium-Heparin Gel⁺
Clinical Equivalence on Siemens Atellica Analyzers

Scheer F.[1], Seipelt C. G.[2], Zwanziger D[3], Wagner B[4]

[1] SARSTEDT AG & Co. KG, Research & Development, Nümbrecht
[2] SARSTEDT AG & Co. KG, Product Management, Nümbrecht
[3] University Hospital Essen, Department of Endocrinology, Diabetes and Metabolism, Division of Laboratory Research, Hufelandstraße 55, 45147 Essen
[4] University Hospital Essen, Department of Clinical Chemistry, Hufelandstraße 55, 45147 Essen

The clinical equivalence of the S-Monovette® Lithium-Heparin Gel⁺ in comparison to the S-Monovette® Lithium Heparin Gel was shown in a study on 52 frequently requested clinical-chemical and immunological parameters in plasma on Siemens Atellica analyzers. If there is a measurement bias between the S-Monovette® Lithium-Heparin Gel⁺ S-Monovette® Lithium-Heparin Gel, they are within the acceptance limit. The S-Monovette® Lithium-Heparin Gel⁺ is thus a blood collection system that absolutely meets the high demands of today's medical laboratory diagnostics and also enables short centrifugation times of up to 4 minutes.

Introduction

Turn-Around-Time (TAT) is an important factor in the laboratory process, especially in emergency diagnostics. An essential component of TAT is the centrifugation time. With the SARSTEDT S-Monovette® Lithium-Heparin (LH) Gel⁺ it is possible to reduce the centrifugation time considerably, e.g. from 10 to 5 minutes at 3000 x g. The time gained accelerates the therapy decision and is, thus, a benefit for patient care. In this study, the S-Monovette® Lithium-Heparin Gel⁺ is compared with the S-Monovette® Lithium-Heparin gel for 53 frequently requested clinical-chemical and immunological parameters on Siemens Atellica analyzers.

Contact address:
SARSTEDT AG & Co. KG | Sarstedtstraße 1 | 51588 Nümbrecht | Germany
Mail: info@sarstedt.com | Tel: (+49) 0 22 93 305 0 | Fax: (+49) 0 22 93 305 24 70

Materials and methods

Venous blood was taken from 58 adult donors at the University Hospital Essen. A Safety-Multifly® needle 20 G (REF 85.1637.235) was used to collect blood into a S-Monovette® LH Gel⁺ 4.9 ml (REF 04.1954) and a S-Monovette® LH Gel 4.9 ml (REF 04.1940) in alternated sequence. The S-Monovette® LH Gel systems were centrifuged at 3000 x g for 10 minutes and S-Monovette® LH Gel⁺ systems at 3500 x g for 4 minutes within 30 minutes post blood draw, plasma was collected and stored at -20 °C until analysis for 4 to 6 months. Blood was collected over a timeframe of 11 weeks from 38 female and 20 male donors. The measurement was performed on a Siemens Atellica™ IM module.

Evaluation

The evaluation of the data was based on recommendations of CLSI EP09-A3 2013 [1]. The values measured of the S-Monovette® LH Gel+ and the reference values from the S-Monovette® LH Gel were plotted against each other and a linear regression was calculated according to Passing-Bablok (Fig. 2, red line) [2]. The black dashed line corresponds to the ideal value without deviations. Measurement pairs of which one or both values were outside the measurement range of the respective method were not considered. The deviation in clinically relevant areas and in respect of the median of the measured values was calculated using the obtained straight line equation (Fig. 2, green lines).

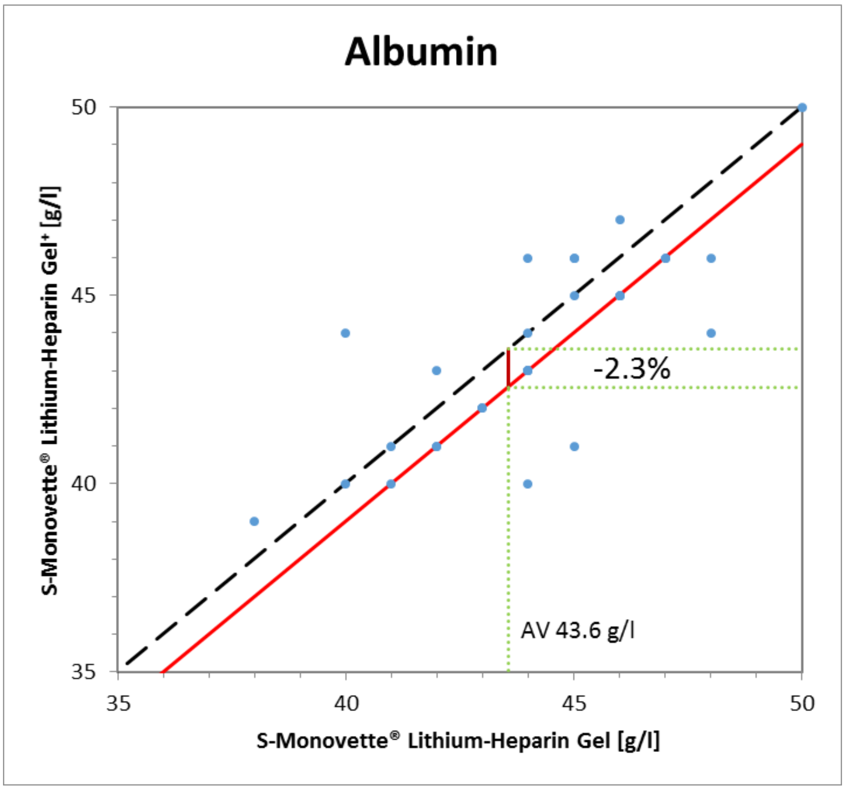


Fig. 1 Evaluation via linear regression using Albumin as an example

Acceptance limits

The percentage acceptance limits were taken from Rili-BÄK [3] or Westgard [4]. The absolute acceptance limits were calculated either based on the mean value of the measured values and the percentage acceptance limit, or on the basis of the method error. The extent to which these acceptance limits can be transferred to an institution’s in-house laboratory should be assessed individually. The manufacturer accepts no liability to this effect.

Results and discussion

The results of the regression are presented in Table 1. Only for LDH the bias is above the acceptance limit for two relevant points. This is most likely the result of the different centrifugation conditions for the tubes, since LDH is susceptible to shear force [5].

Table 1 Comparison of S-Monovette® Lithium-Heparin Gel$^+$ and S-Monovette® Lithium-Heparin Gel, values beyond the target range are marked in bold

Parameters	Unit	N	Slope (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit
					Value	Error		Value	Error		Value	Error		
						%	Abs		%	Abs		%	Abs	%
Albumin	g/dL	56	0.991 (0.895; 1.074)	0.055 (-0.308; 0.463)	3.20	0.8	0.03	4.80	0.2	0.01	4.4	0.4	0.02	12.5
AP	U/L	56	1.000 (1.000; 1.043)	0.000 (-3.053; 0.000)	46	0.0	0.0	116	0.0	0.0	92.0	0.0	0.0	11.0
GPT (ALT)	U/L	45	1.000 (1.000; 1.111)	0.000 (-1.556; 0.000)	10	0.0	0.0	49	0.0	0.0	17.0	0.0	0.0	11.5
GOT (AST)	U/L	56	1.000 (1.000; 1.048)	***1.000 (0.024; 1.000)***	10	10.0	1.0	34	2.9	1.0	27.3	3.7	1.0	11.5
Complement C3	g/L	55	0.979 (0.914; 1.035)	0.023 (-0.054; 0.111)	0.800	0.9	0.007	1.600	-0.6	-0.010	1.4	-0.4	-0.006	8.4
Calcium	mmol/L	56	1.000 (0.885; 1.125)	0.005 (-0.266; 0.249)	2.08	0.2	0.00	2.65	0.2	0.00	2.2	0.2	0.00	7.5
CHE	U/mL	56	0.990 (0.963; 1.016)	0.090 (-0.145; 0.369)	7.000	0.3	0.021	19.000	-0.5	-0.098	10.5	-0.1	-0.014	9.8
Cholesterol	mg/dL	55	0.970 (0.944; 1.000)	***6.394 (1.000; 10.889)***	200	0.2	0.3	239	-0.4	-0.8	204.2	0.1	0.2	7.0
CK	U/L	54	1.000 (0.960; 1.054)	***3.000 (0.342; 5.200)***	34	8.8	3.0	171	1.8	3.0	67.4	4.5	3.0	11.0
Chloride	mmol/L	55	1.000 (0.833; 1.083)	0.000 (-8.667; 17.667)	98	0.0	0.0	107	0.0	0.0	106.1	0.0	0.0	4.5
Cortisol	nmol/L	53	0.998 (0.960; 1.039)	2.666 (-10.236; 15.970)	145.0	1.6	2.3	620.0	0.2	1.2	413.5	0.4	1.7	16.0
Creatinin	mg/dL	56	1.000 (0.981; 1.043)	0.010 (-0.032; 0.021)	0.55	1.8	0.01	1.30	0.8	0.01	0.8	1.2	0.01	11.5
CRP	mg/dL	20	1.000 (0.929; 1.000)	0.000 (0.000; 0.043)	0.5	0.0	0.0	1.0	0.0	0.0	1.5	0.0	0.0	13.5
HDL	mg/dL	55	0.979 (0.953; 1.008)	0.856 (-0.243; 2.143)	40.0	0.0	0.0	60.0	-0.7	-0.4	50.0	-0.4	-0.2	13.0
Bilirubin (direct)	mg/dL	46	1.000 (0.969; 1.047)	-0.002 (-0.010; 0.005)	0.200	-1.0	-0.002	0.300	-0.7	-0.002	0.2	-1.0	-0.002	22.0
LDL	mg/dL	55	0.977 (0.951; 1.008)	3.184 (-0.850; 6.554)	100.0	0.9	0.9	159.0	-0.3	-0.5	139.9	0.0	0.0	9.0
Estradiol	pg/mL	39	1.032 (0.907; 1.122)	1.557 (-3.647; 4.547)	39.80	7.1	2.84	356.70	3.7	13.07	37.0	7.4	2.75	22.0
Ferritin	ug/L	56	1.000 (0.983; 1.011)	0.500 (-0.091; 1.052)	9.0	5.6	0.5	322.0	0.2	0.5	110.8	0.5	0.5	13.5
Folate	ng/mL	51	0.928 (0.852; 1.014)	1.013 (-0.039; 2.103)	5.38	11.7	0.63	10.00	3.0	0.30	14.5	-0.2	-0.03	25.0
FSH	IU/L	53	***0.974 (0.964; 0.994)***	0.215 (-0.017; 0.337)	1.40	12.7	0.18	116.30	-2.5	-2.86	36.4	-2.1	-0.75	14.0
fT3	pmol/L	54	0.986 (0.942; 1.035)	0.033 (-0.189; 0.231)	3.50	-0.4	-0.01	6.50	-0.8	-0.05	4.8	-0.7	-0.03	13.0
fT4	pmol/L	54	0.976 (0.918; 1.044)	0.503 (-0.469; 1.435)	11.50	1.9	0.22	22.70	-0.2	-0.05	16.5	0.6	0.10	13.0

Parameters	Unit	N	Slope (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit
					Value	Error		Value	Error		Value	Error		
						%	Abs		%	Abs		%	Abs	%
GGT	U/L	56	1.000 (1.000; 1.022)	0.000 (-0.391; 0.000)	38	0.0	0.0	73	0.0	0.0	88.1	0.0	0.0	11.5
Glucose	mg/dL	56	1.004 (1.000; 1.026)	-0.497 (-3.179; 0.000)	74	-0.3	-0.2	106	-0.1	-0.1	115.9	-0.1	-0.1	11.0
Haptoglobin	g/L	52	1.017 (0.994; 1.038)	-0.016 (-0.040; 0.009)	0.400	-2.3	-0.009	2.400	1.1	0.026	1.4	0.6	0.008	20.0
IgA	g/L	56	0.998 (0.974; 1.022)	-0.027 (-0.076; 0.022)	0.400	-7.0	-0.028	3.500	-1.0	-0.034	2.2	-1.4	-0.032	12.0
IgG	g/L	56	0.995 (0.963; 1.032)	-0.002 (-0.376; 0.293)	6.500	-0.5	-0.033	16.000	-0.5	-0.077	9.7	-0.5	-0.047	10.0
IgM	g/L	56	1.003 (0.985; 1.019)	-0.003 (-0.015; 0.014)	0.400	-0.5	-0.002	3.000	0.2	0.006	1.0	0.0	0.000	13.0
Phosphorous	mg/dL	56	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	2.4	0.0	0.0	5.1	0.0	0.0	3.1	0.0	0.0	9.0
Iron	µg/dL	56	1.000 (0.971; 1.005)	0.000 (-0.373; 2.044)	50	0.0	0.0	175	0.0	0.0	77.3	0.0	0.0	30.7
Potassium	mmol/L	55	1.037 (0.950; 1.140)	-0.126 (-0.521; 0.215)	3.40	0.0	0.00	4.50	0.9	0.04	4.0	0.6	0.02	4.5
LDH	U/L	56	***1.203 (1.059; 1.314)***	-19.581 (-43.729; 6.706)	120	4.0	4.7	246	***12.3***	30.3	216.7	***11.2***	24.3	9.0
LH	IU/L	54	0.992 (0.976; 1.001)	0.024 (-0.028; 0.087)	0.50	4.0	0.02	76.30	-0.8	-0.62	17.1	-0.7	-0.12	15.0
Lipase	U/L	55	1.000 (0.944; 1.063)	-1.000 (-3.063; 1.444)	12	-8.3	-1.0	53	-1.9	-1.0	37.9	-2.6	-1.0	11.0
Magnesium	mmol/L	56	0.939 (0.857; 1.000)	***0.054 (0.005; 0.119)***	0.66	2.1	0.01	1.07	-1.0	-0.01	0.8	0.7	0.01	7.5
Sodium	mmol/L	55	1.000 (0.846; 1.333)	0.000 (-45.667; 21.231)	136	0.0	0.0	145	0.0	0.0	136.7	0.0	0.0	3.0
p-Amylase	U/L	54	1.000 (1.000; 1.041)	0.000 (-0.959; 0.000)	13	0.0	0.0	53	0.0	0.0	28.7	0.0	0.0	7.0
Procalcitonin	ng/mL	47	1.000 (0.941; 1.000)	0.000 (0.000; 0.003)	0.50	0.0	0.00	1.00	0.0	0.00	0.1	0.0	0.00	18.0
Progesterone	ng/mL	50	1.002 (0.973; 1.128)	0.020 (-0.008; 0.033)	0.28	7.2	0.02	25.60	0.3	0.07	0.7	3.1	0.02	17.0
RF	IU/mL	28	1.024 (0.966; 1.141)	-0.237 (-1.163; 0.372)	14.0	0.7	0.1	30.0	1.6	0.5	11.0	0.2	0.0	13.5
Bilirubin (total)	mg/dL	55	1.000 (1.000; 1.000)	0.000 (0.000; 0.000)	0.2	0.0	0.0	1.1	0.0	0.0	0.5	0.0	0.0	22.0
HCG	mIU/mL	30	1.000 (0.967; 1.056)	0.050 (-0.006; 0.107)	1.5	3.3	0.0	4.2	1.2	0.0	3.1	1.6	0.0	14.0
HS Troponin I	ng/L	28	0.998 (0.933; 1.042)	-0.046 (-0.349; 0.312)	45.00	-0.3	-0.13	100.00	-0.2	-0.22	16.2	-0.5	-0.08	20.0
Total Protein	g/dL	56	0.928 (0.844; 1.033)	0.490 (-0.218; 1.049)	5.70	1.3	0.08	8.20	-1.3	-0.10	6.6	0.2	0.02	6.0

Parameters	Unit	N	Slope (95% confidence intervals)	Axis segment (95% confidence intervals)	Deviation in lower range			Deviation in upper range			Deviation at mean value			Acceptance limit
					Value	Error		Value	Error		Value	Error		
						%	Abs		%	Abs		%	Abs	%
Transferrin	g/L	56	0.994 (0.946; 1.038)	0.005 (-0.088; 0.114)	2.15	-0.4	-0.01	3.80	-0.5	-0.02	2.4	-0.4	-0.01	8.0
Triglyzeride	mg/dL	55	1.007 (0.995; 1.027)	-0.741 (-3.263; 0.968)	150	0.2	0.3	500	0.5	2.7	194.3	0.3	0.6	9.0
TSH	mU/L	53	0.997 (0.979; 1.009)	0.002 (-0.003; 0.019)	0.550	0.0	0.000	4.780	-0.3	-0.012	1.3	-0.2	-0.002	13.5
Testosterone	nmol/L	52	0.985 (0.975; 1.000)	0.015 (0.000; 0.030)	0.42	2.2	0.01	27.35	-1.4	-0.38	6.0	-1.2	-0.07	20.5
Uric Acid	mg/dL	56	1.000 (0.969; 1.000)	0.000 (0.000; 0.167)	3.1	0.0	0.0	9.2	0.0	0.0	5.7	0.0	0.0	7.0
Urea	mg/dL	56	1.025 (0.974; 1.077)	-0.159 (-0.977; 0.640)	9.0	0.7	0.1	23.0	1.8	0.4	15.5	1.4	0.2	10.5
Vitamin B12	pg/mL	50	1.059 (0.966; 1.147)	-21.317 (-58.985; 16.567)	211	-4.2	-8.8	911	3.6	32.6	499.1	1.7	8.2	25.0
CK-MB	U/L	53	1.086 (0.964; 1.295)	0.026 (-0.913; 0.847)	25.000	8.7	2.172	40.000	8.7	3.460	6.7	9.0	0.602	24.1

Conclusion

The clinical equivalence of the S-Monovette® Lithium-Heparin Gel⁺ and the S-Monovette® Lithium-Heparin Gel is successfully demonstrated for 53 clinical-chemical and immunological analytes in plasma on Siemens Atellica analyzers.

For each change in the process of acquiring analytic data, e.g. sample tube or centrifugation conditions, the laboratory should evaluate the manufacturer's data and its own data to ensure that analyses are not falsified. The manufacturer does not assume any warranty for this.

Literature

[1] CLSI EP09 *Measurement Procedure Comparison and Bias Estimation Using Patient Samples*, Third Edition 2013

[2] Passing H, Bablok W. A new biometrical procedure for testing the equality of measurements from two different analytical methods. Applications of linear regression procedures for method comparison studies in clinical chemistry, Part I. *J Clin Chem Clin Biochem*21(11):709–720 1983

[3] RiliBÄK, Richtlinie der Bundesärztekammer zur Qualitätssicherung 2019

[4] https://www.westgard.com/biodatabase1.htm

[5] Shiragami, N., Unno, H. Effect of shear stress on activity of cellular enzyme in animal cell. *Bioprocess Engineering* 10:43–45 1994

Annex

I. Methods used
II. Diagrams

I. Methods used

Parameter	Method	Parameter	Method
Albumin	*Atellica CH Albumin BCG (Alb)* Absorption spectrometry (bromocresol purple)	Urea	*Atellica CH Urea Nitrogen (UN_c) (serum/plasma)* Absorption spectrometry (urease)
AP	*Atellica CH Alkaline Phosphatase, Concentrated (ALP_2c)* Absorption spectrometry	HCG	*Atellica IM Free Beta Human Chorionic Gonadotropin (FBHCG)* Sandwich-chemiluminescence immunoassay
Estradiol	*Atellica IM Enhanced Estradiol (eE2)* Competitive chemiluminescence immunoassay	HDL	*Atellica CH Direct HDL Cholesterol (D-HDL)* Absorption spectrometry (peroxidase)
Bilirubin (direct)	*Atellica CH Direct Bilirubin 2 (DBil_2)* Absorption spectrometry (vanadate)	HS Troponin I	*Atellica IM High Sensitivity Troponin I (TnIH)* Sandwich-chemiluminescence immunoassay
Bilirubin (total)	*Atellica CH Total Bilirubin_2 (TBil_2)* Absorption spectrometry (vanadate)	IgA	*Atellica CH Immunoglobulin A_2 (IgA_2)* immunoturbidimetry
Complement C3	*Atellica CH Complement C3 (C3)* immunoturbidimetry	IgG	*Atellica CH Immunoglobulin G_2 (IgG_2)* immunoturbidimetry
Calcium	*Atellica CH Calcium (CPC)* Absorption spectrometry (CPC)	IgM	*Atellica CH Immunoglobulin M_2 (IgM_2)* immunoturbidimetry
p-Amylase	*Atellica CH Pancreatic Amylase_2 (serum and plasma)* Absorption spectrometry (Ethyliden-G7-pNP)	Potassium	Indirect IMT

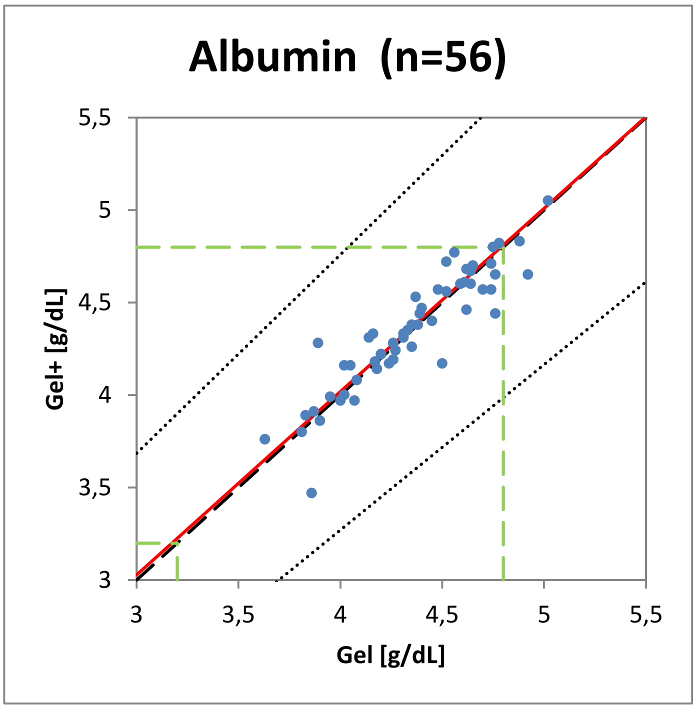
CHE	*Atellica CH Cholinesterase (CHE)* Absorption spectrometry	Creatinin	*Atellica CH Creatinine_2 (Crea_2)* Absorption spectrometry, Jaffe
Chloride	Indirect IMT	LDH	*Atellica CH Lactate Dehydrogenase L-P (LDLP)* Absorption spectrometry
Cholesterol	*Atellica CH Cholesterol_2 (Chol_2)* Absorption spectrometry (peroxidase)	LDL	*Atellica CH LDL Cholesterol Direct (DLDL)* Absorption spectrometry (peroxidase)
CK	*Atellica CH Creatine Kinase (CK_L)* Absorption spectrometry (hexokinase-G6PD)	LH	*Atellica IM Luteinizing Hormone (LH)* Sandwich-chemiluminescence immunoassay
CK-MB	*Atellica IM Creatine Kinase MB (CKMB)* Absorption spectrometry	Lipase	*Atellica CH Lipase (Lip)* Absorption spectrometry (DGGMR)
Cortisol	*Atellica IM Cortisol (Cor)* Competitive chemiluminescence immunoassay	Magnesium	*Atellica CH Magnesium (Mg) (serum/plasma)* Absorption spectrometry (Xylidyl blue)
CRP	*Atellica CH C-Reactive Protein_2 (CRP_2)* immunoturbidimetry	Sodium	Indirect IMT
Total Protein	*Atellica CH Total Protein II (TP)* Absorption spectrometry (Biuret)	Phosphorous	*Atellica CH Inorganic Phosphorus (IP)* Absorption spectrometry (ammonium molybdate)
Ferritin	*Atellica IM Ferritin (Fer)* Sandwich-chemiluminescence immunoassay	Procalcitonin	*Atellica IM BRAHMS Procalcitonin (PCT)* Sandwich-chemiluminescence immunoassay
Folate	*Atellica IM Folate (Fol)* Sandwich-chemiluminescence immunoassay	Progesterone	*Atellica IM Progesterone (PRGE)* Competitive chemiluminescence immunoassay
fT3	*Atellica IM Free Triiodothyronine (FT3)* Competitive chemiluminescence immunoassay	RF	*Atellica CH Rheumatoid Factor (RF)* immunoturbidimetry
fT4	*Atellica IM Free Thyroxine (FT4)* Competitive chemiluminescence immunoassay	Testosterone	*Atellica IM Testosterone II (TSTII)* Competitive chemiluminescent immunoassay

FSH	*Atellica IM Follicle Stimulating Hormone (FSH)* Competitive chemiluminescence immunoassay	Transferrin	*Atellica CH Transferrin (Trf)* Immunoturbidimetry
GGT	*Atellica CH Gamma-Glutamyl Transferase (GGT)* Absorption spectrometry	Triglyceride	*Atellica CH Triglycerides (concentrated) (Trig)* Absorption spectrometry (peroxidase)
Glucose	*Atellica CH Glucose Hexokinase_3 (GluH_3)* Absorption spectrometry (Hexokinase)	TSH	*Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)* Competitive chemiluminescence immunoassay
GOT (AST)	*Atellica CH Aspartate Aminotransferase (AST)* Absorption spectrometry, enzymatic	Iron	*Atellica CH Iron_2 (Iron_2)* Absorption spectrometry (ferrozin)
GPT (ALT)	*Atellica CH Alanine Aminotransferase (ALT)* Absorption spectrometry (enzymatic)	Uric Acid	*Atellica CH Uric Acid (UA)* Absorption spectrometry
Haptoglobin	*Atellica CH Haptoglobin* immunoturbidimetry	Vitamin B12	*Atellica IM Vitamin B12 (VB12)* Competitive chemiluminescence immunoassay

ELISA: enzyme-linked immunosorbent assay; IMT: Integrated Multisensor Technology; PETINIA: particle-enhanced turbidimetric inhibition immunoassay

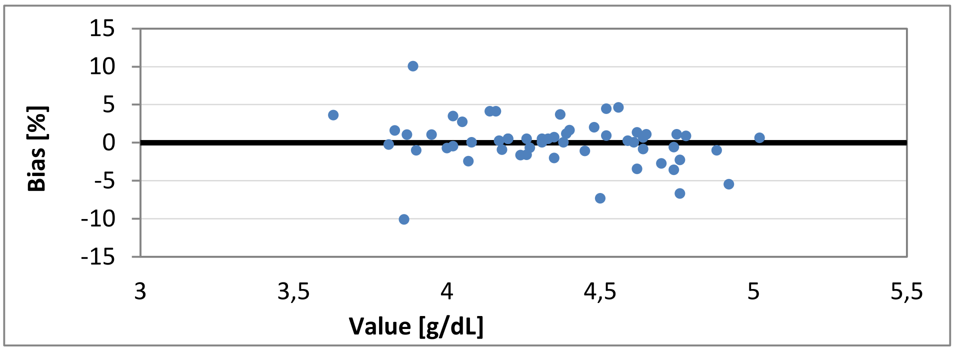
II. Diagrams

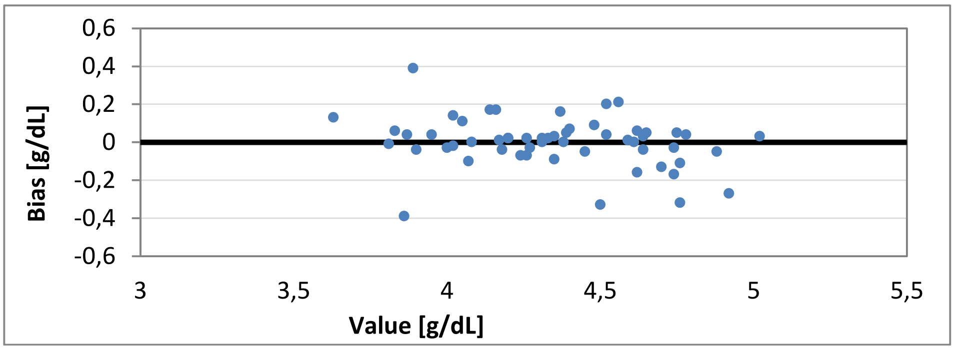
Albumin (n= 56)



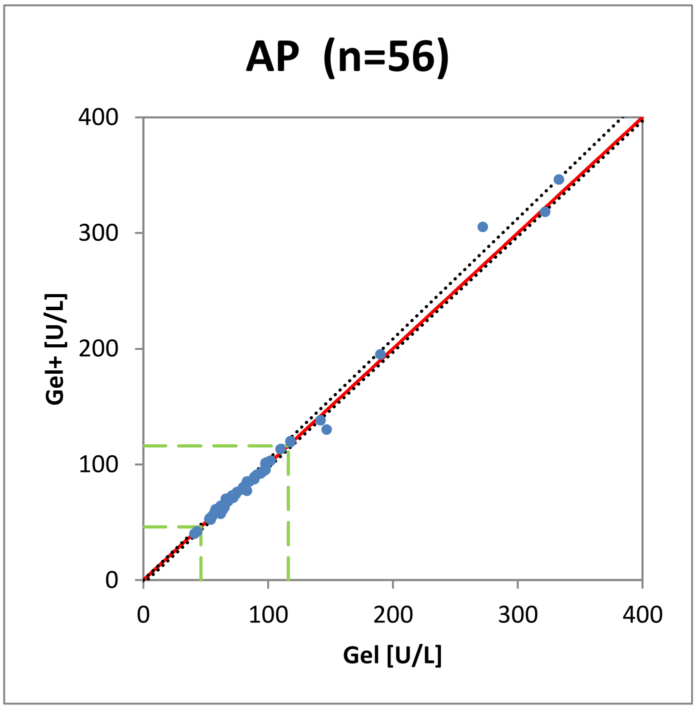
Passing-Bablok Regression	
Slope	0.9910
95 % CI	1.0741
95 % CI	0.8947
Axis	0.0546
95 % CI	0.4626
95 % CI	-0.3080

bias at relevant points		
	g/dL	bias
Average	4.4	0.4%
upper level	3.2	0.8%
lower level	4.8	0.2%
acceptable bias		12.5%



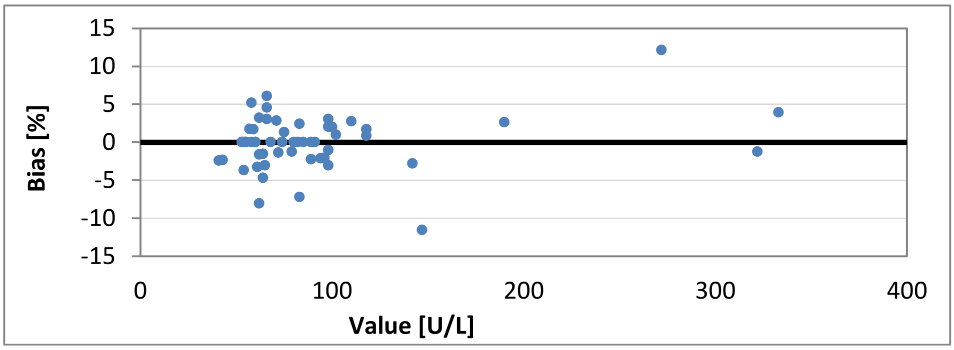


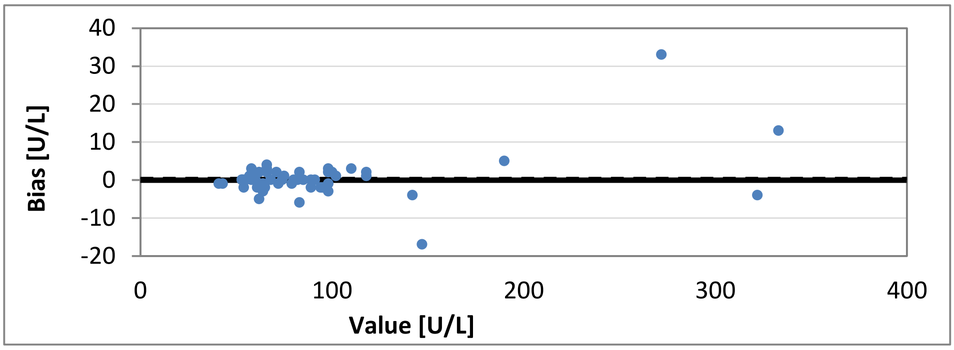
AP (n= 56)



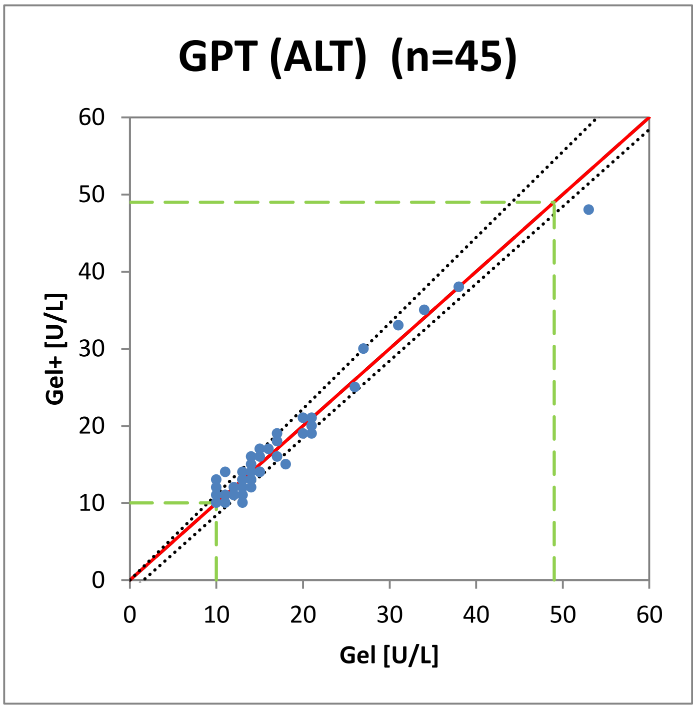
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0426
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	-3.0532

bias at relevant points		
	U/L	bias
Average	92.2	0.0%
upper level	46	0.0%
lower level	116	0.0%
acceptable bias		11.0%



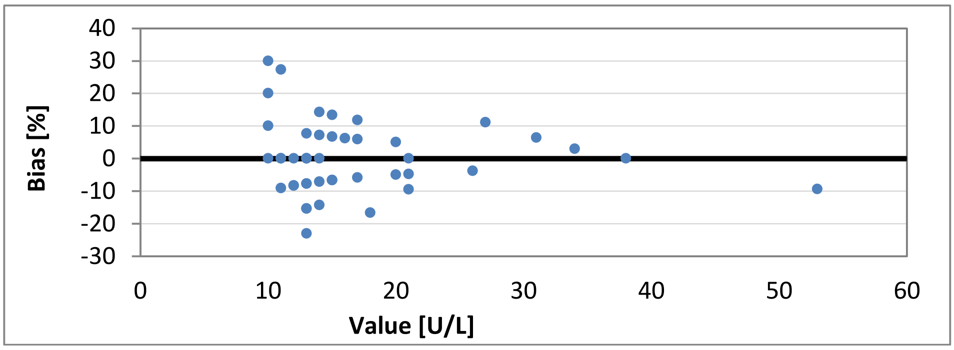


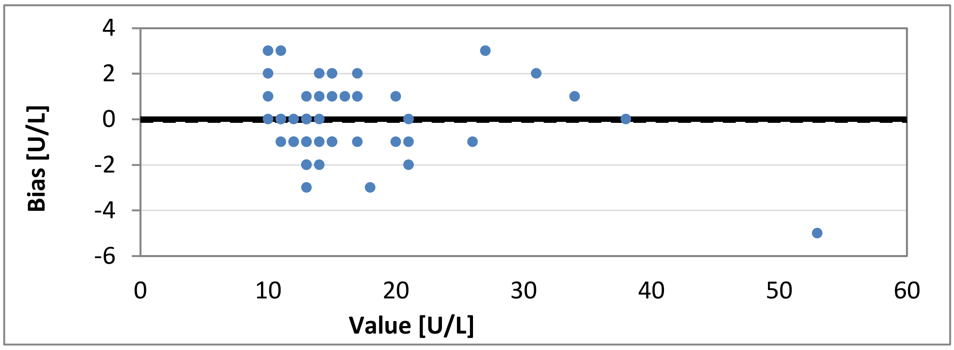
GPT (ALT) (n= 45)



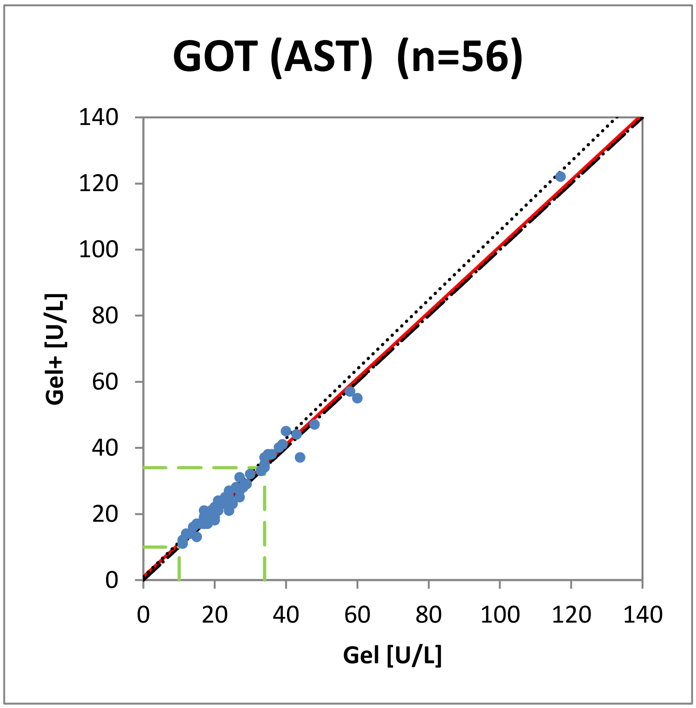
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.1111
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	-1.5556

bias at relevant points		
	U/L	bias
Average	16.9	0.0%
upper level	10	0.0%
lower level	49	0.0%
acceptable bias		11.5%



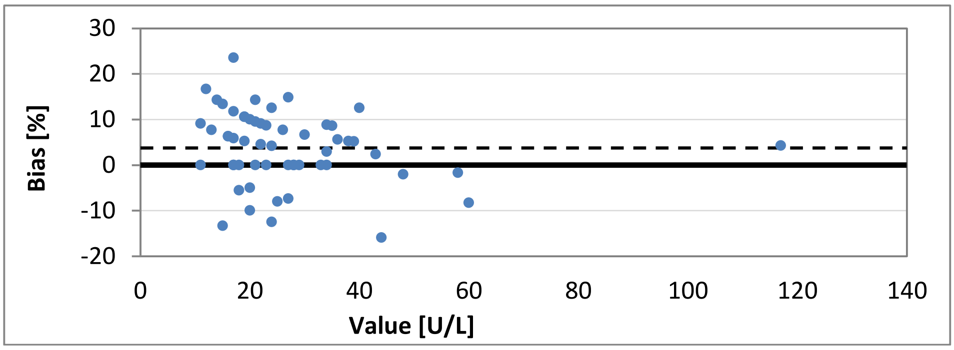


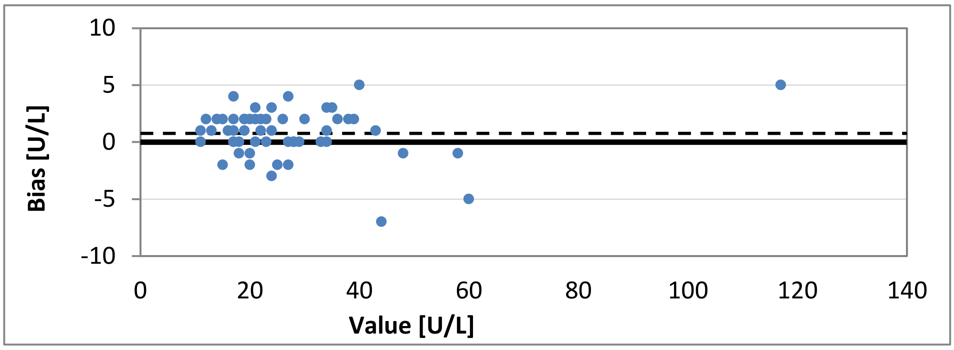
GOT (AST) (n= 56)



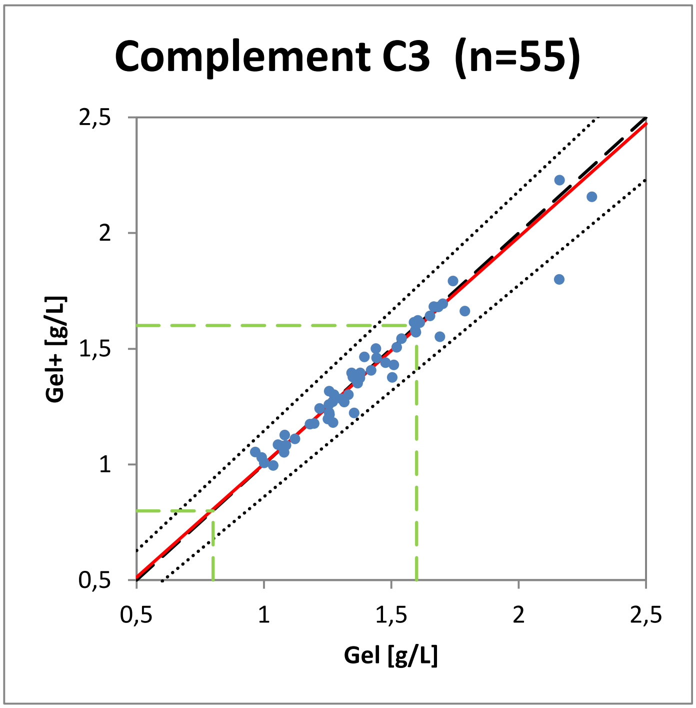
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0476
95 % CI	1.0000
Axis	1.0000
95 % CI	1.0000
95 % CI	0.0238

bias at relevant points		
	U/L	bias
Average	27.6	3.6%
upper level	10	10.0%
lower level	34	2.9%
acceptable bias		11.5%



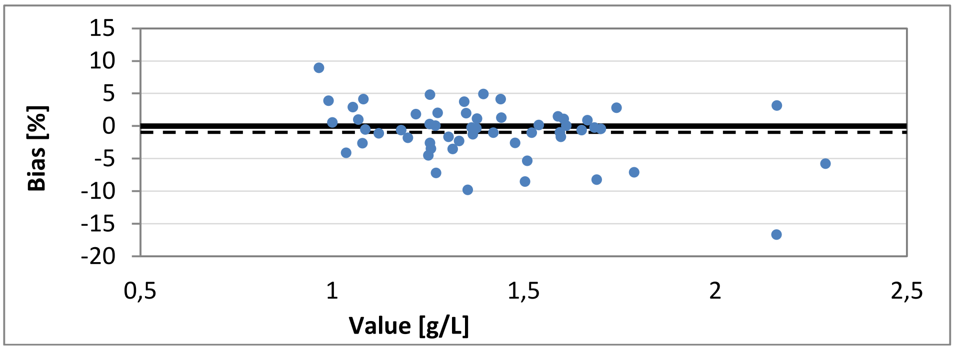


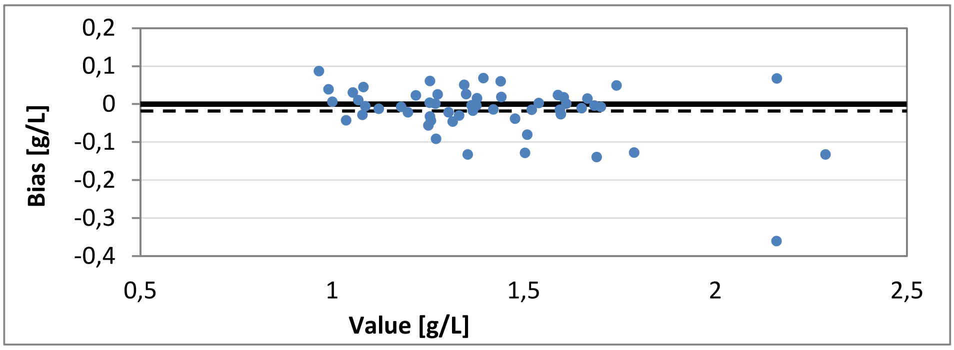
Complement C3 (n= 55)



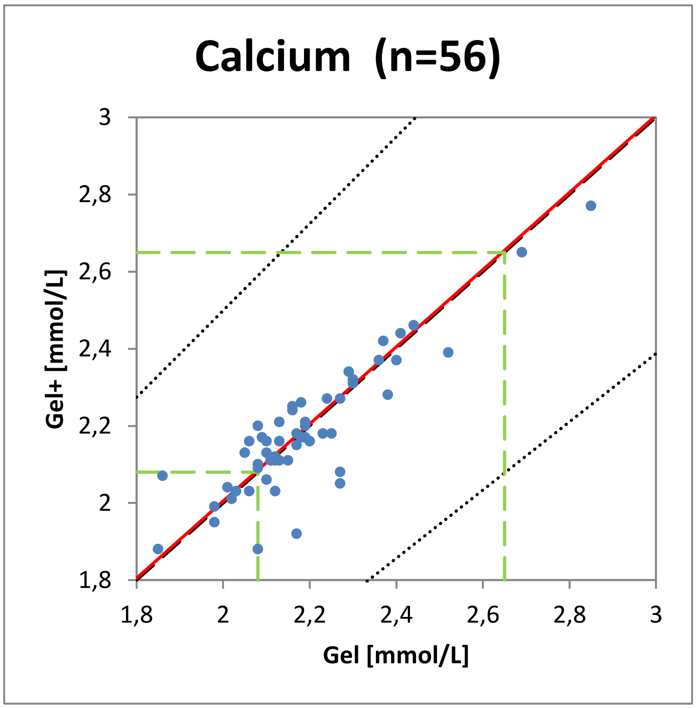
Passing-Bablok Regression	
Slope	0.9795
95 % CI	1.0353
95 % CI	0.9143
Axis	0.0233
95 % CI	0.1106
95 % CI	-0.0536

bias at relevant points		
	g/L	bias
Average	1.4	-0.4%
upper level	0.8	0.9%
lower level	1.6	-0.6%
acceptable bias		8.4%



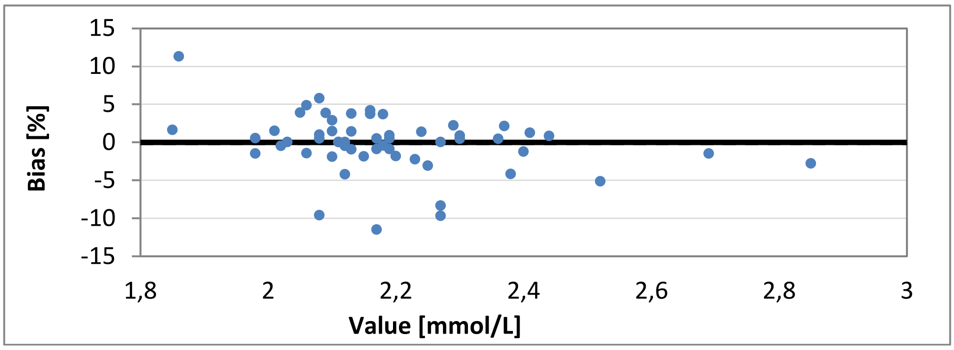


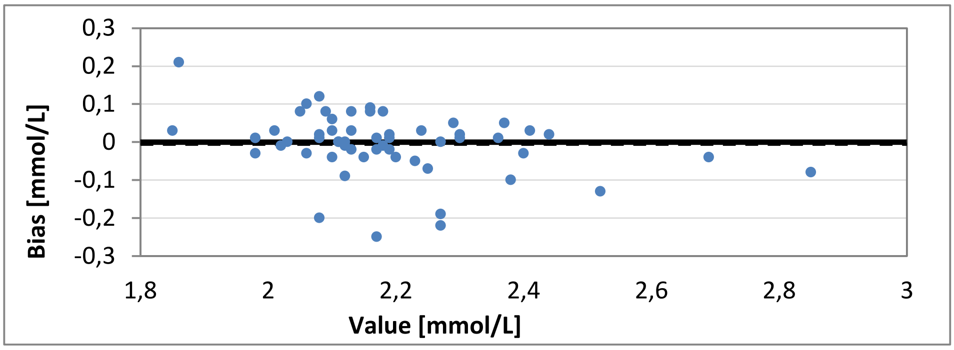
Calcium (n= 56)



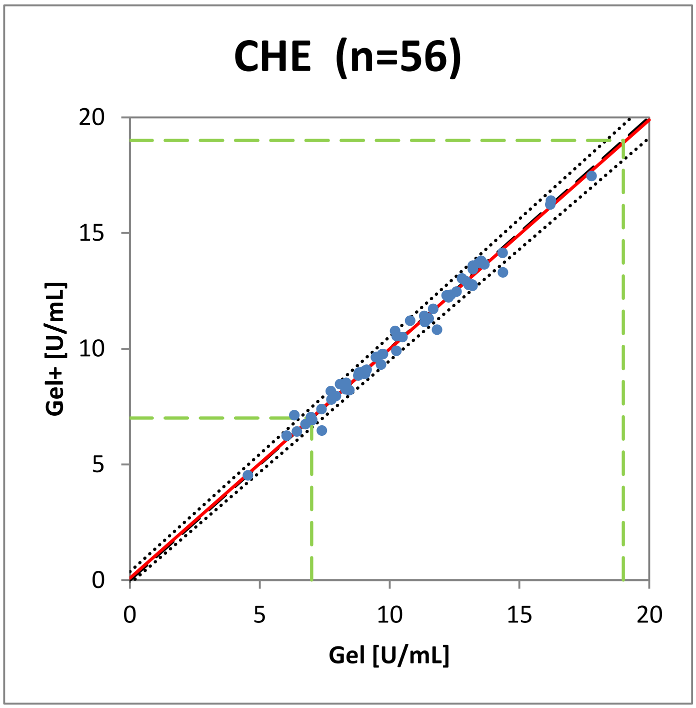
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.1250
95 % CI	0.8846
Axis	0.0050
95 % CI	0.2494
95 % CI	-0.2662

bias at relevant points		
	mmol/L	bias
Average	2.2	0.2%
upper level	2.08	0.2%
lower level	2.65	0.2%
acceptable bias		7.5%



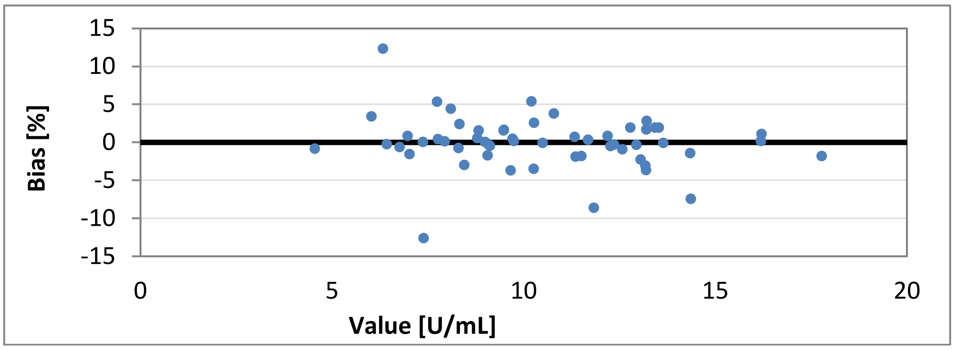


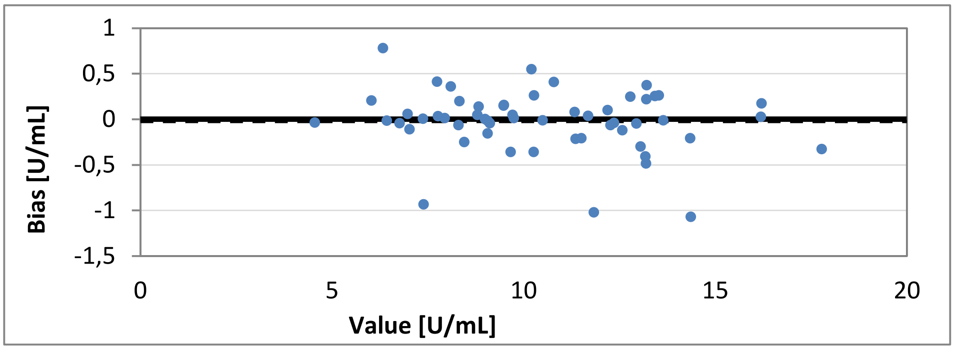
CHE (n= 56)



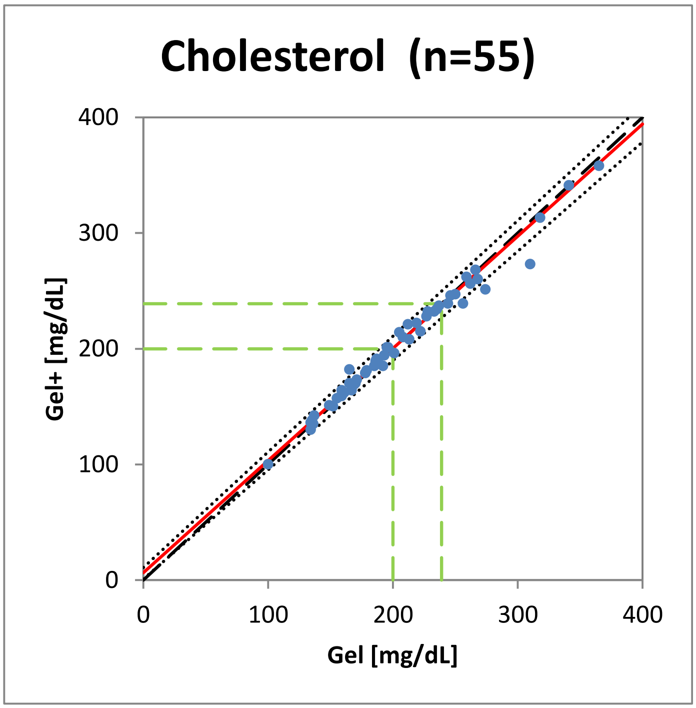
Passing-Bablok Regression	
Slope	0.9901
95 % CI	1.0161
95 % CI	0.9633
Axis	0.0901
95 % CI	0.3691
95 % CI	-0.1446

bias at relevant points		
	U/mL	bias
Average	10.5	-0.1%
upper level	7	0.3%
lower level	19	-0.5%
acceptable bias		9.8%



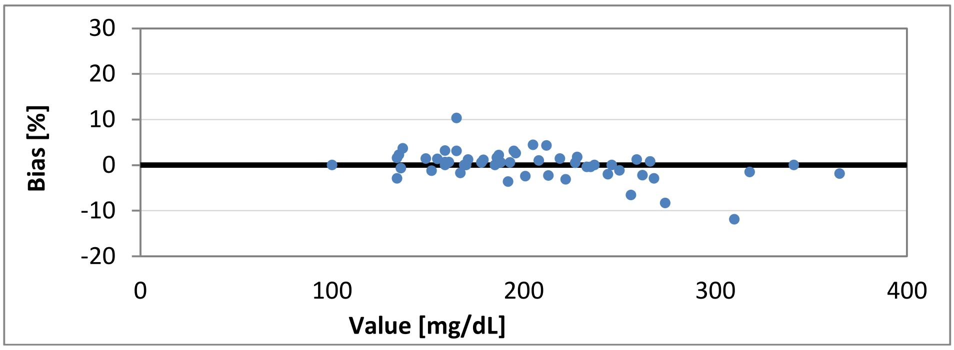


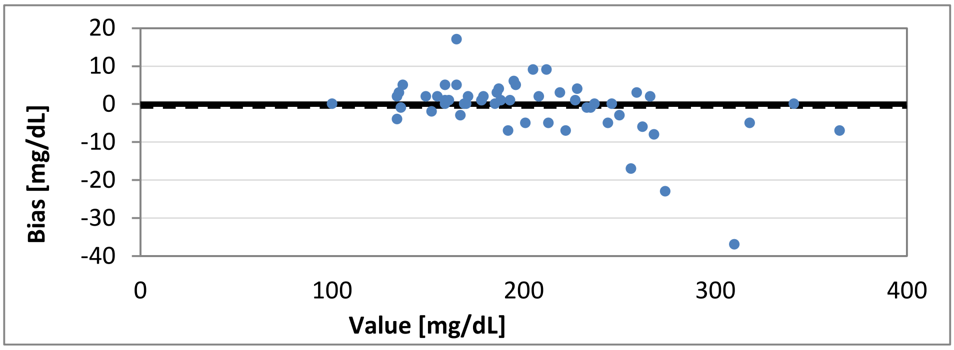
Cholesterol (n= 55)



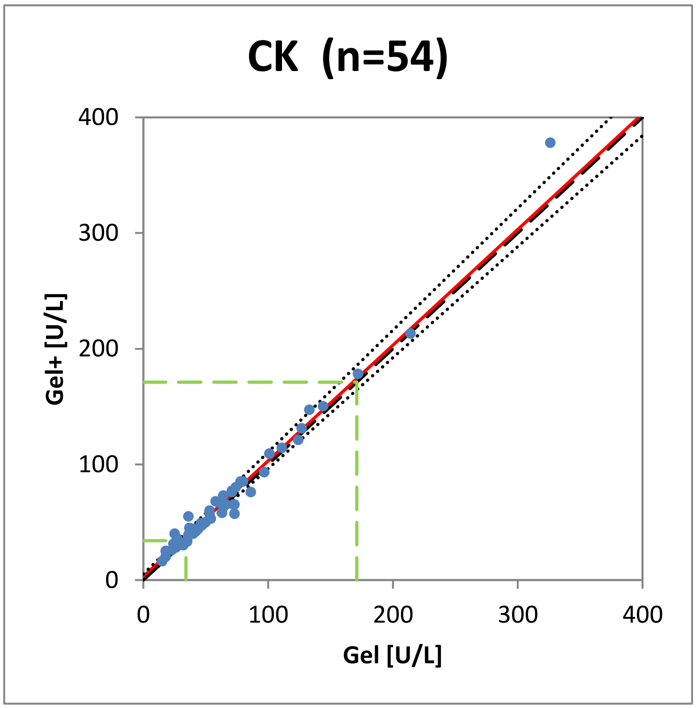
Passing-Bablok Regression	
Slope	0.9697
95 % CI	1.0000
95 % CI	0.9444
Axis	6.3939
95 % CI	10.8889
95 % CI	1.0000

bias at relevant points		
	mg/dL	bias
Average	203.8	0.1%
upper level	200	0.2%
lower level	239	-0.4%
acceptable bias		7.0%



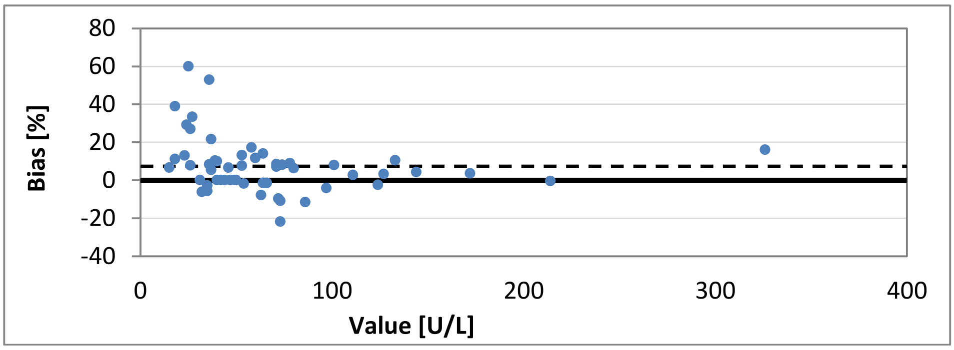


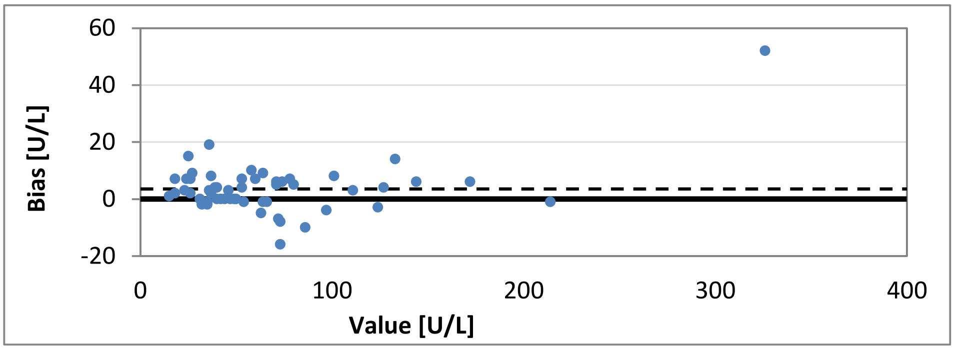
CK (n= 54)



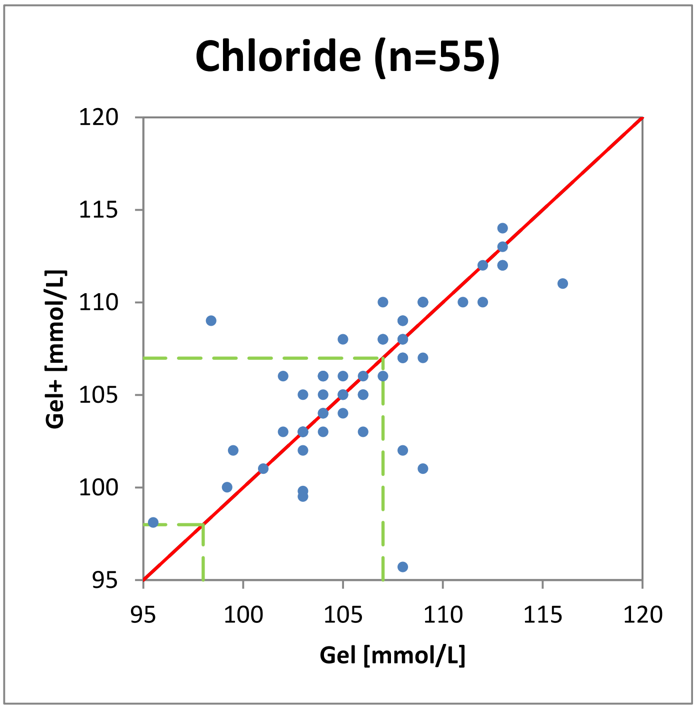
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0543
95 % CI	0.9600
Axis	3.0000
95 % CI	5.2000
95 % CI	0.3424

bias at relevant points		
	U/L	bias
Average	69.2	4.3%
upper level	34	8.8%
lower level	171	1.8%
acceptable bias		11.0%



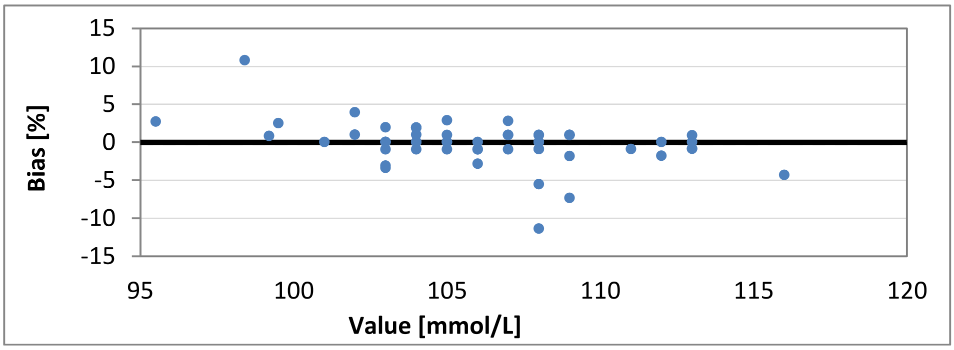


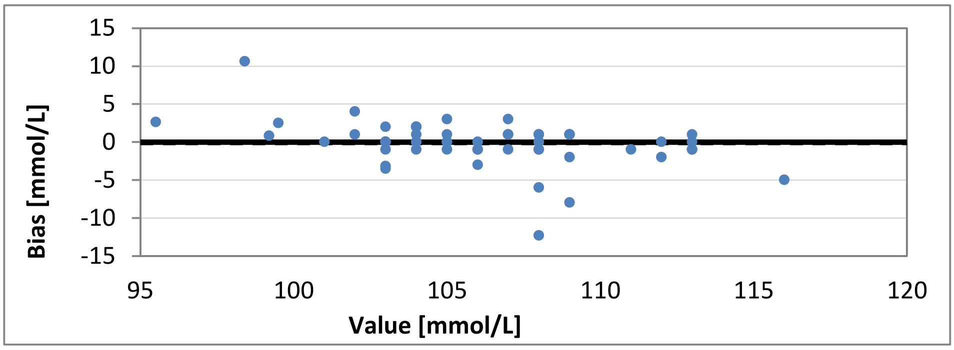
Chloride (n= 55)



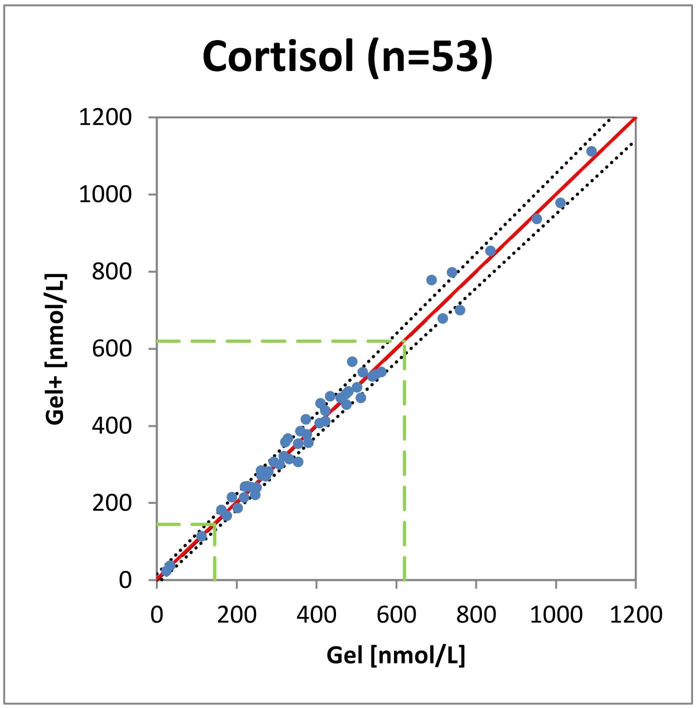
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0833
95 % CI	0.8333
Axis	0.0000
95 % CI	17.6667
95 % CI	-8.6667

bias at relevant points		
	mmol/L	bias
Average	106.0	0.0%
upper level	98	0.0%
lower level	107	0.0%
acceptable bias		4.5%



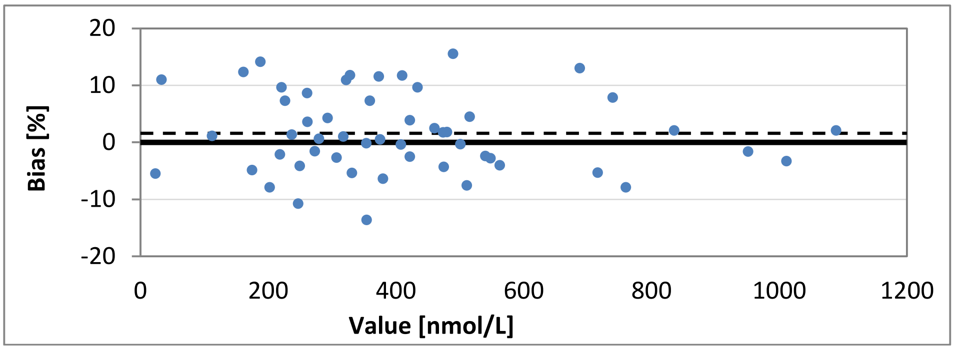


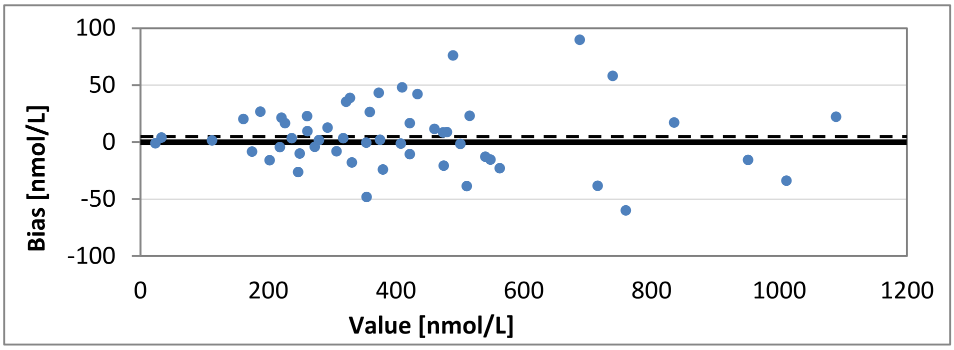
Cortisol (n= 53)



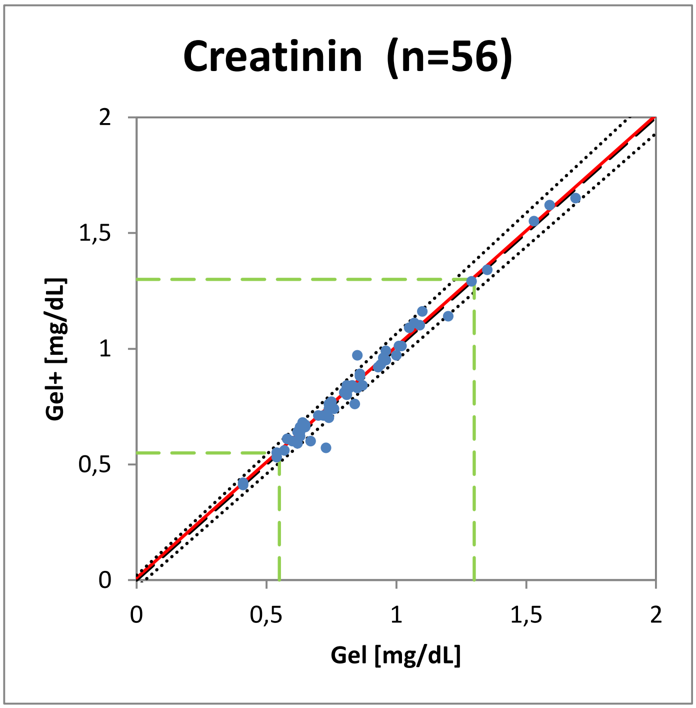
Passing-Bablok Regression	
Slope	0.9977
95 % CI	1.0387
95 % CI	0.9596
Axis	2.6661
95 % CI	15.9702
95 % CI	-10.2363

bias at relevant points		
	nmol/L	bias
Average	415.9	0.4%
upper level	145	1.6%
lower level	620	0.2%
acceptable bias		16.0%



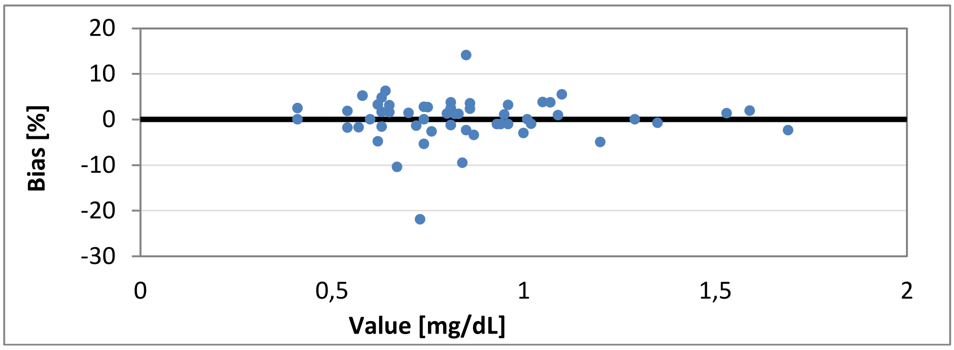


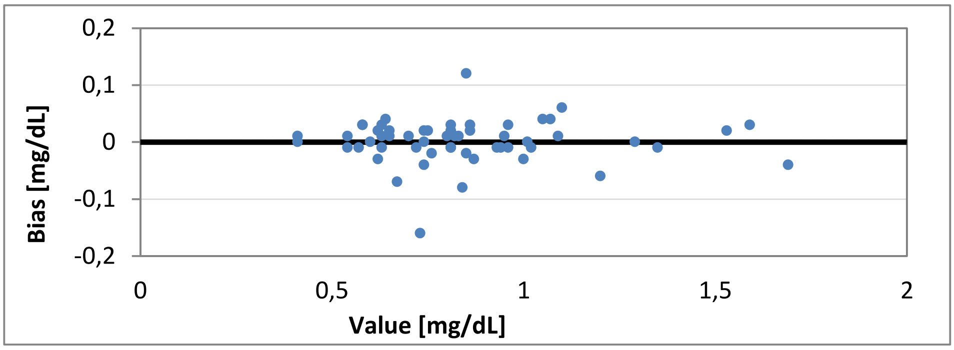
Creatinin (n= 56)



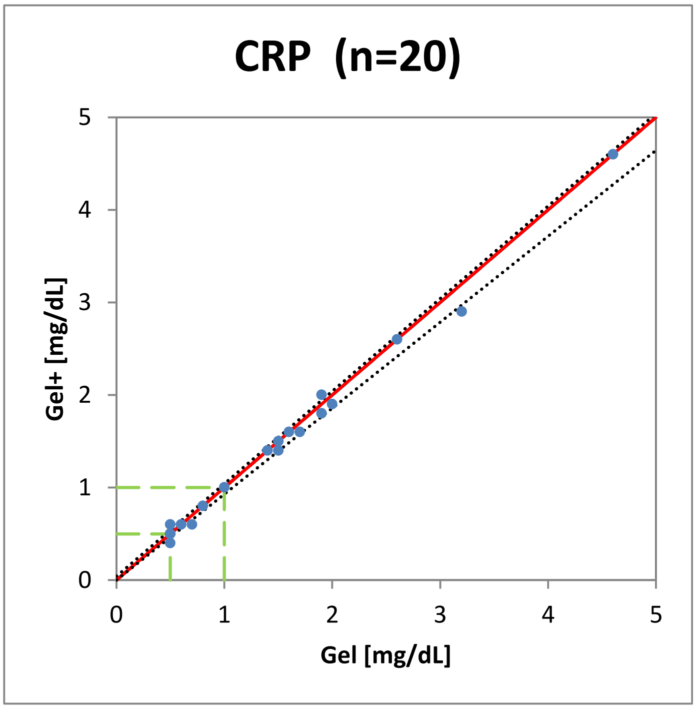
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0435
95 % CI	0.9811
Axis	0.0100
95 % CI	0.0210
95 % CI	-0.0317

bias at relevant points		
	mg/dL	bias
Average	0.8	1.2%
upper level	0.55	1.8%
lower level	1.3	0.8%
acceptable bias		11.5%



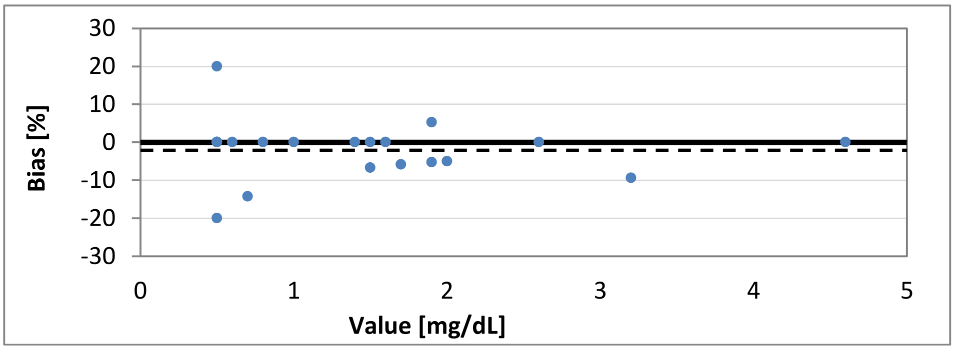


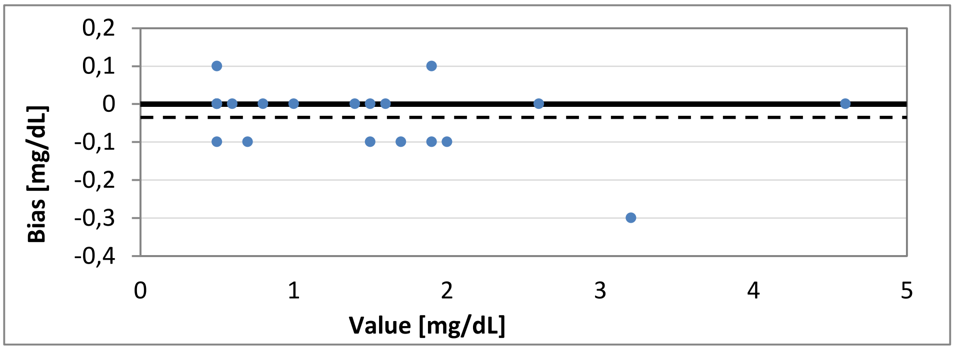
CRP (n= 20)



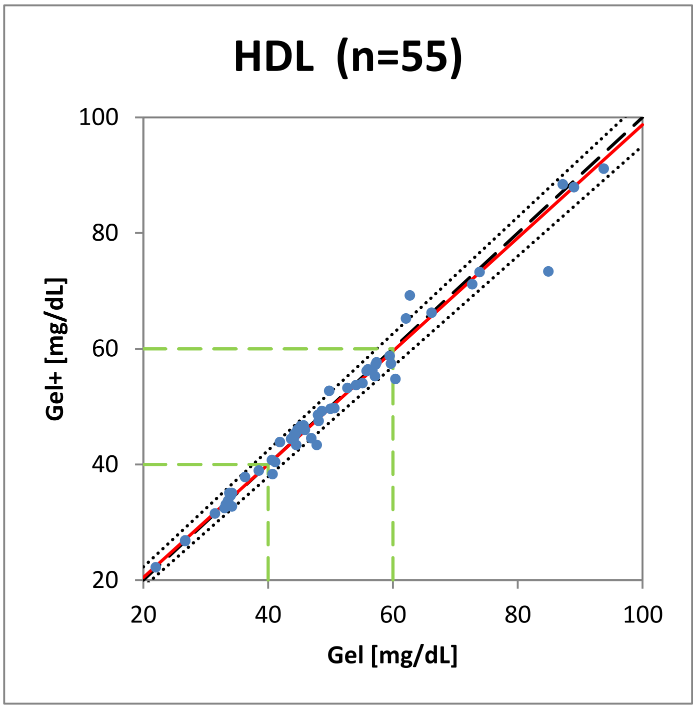
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0000
95 % CI	0.9286
Axis	0.0000
95 % CI	0.0429
95 % CI	0.0000

bias at relevant points		
	mg/dL	bias
Average	1.5	0.0%
upper level	0.5	0.0%
lower level	1	0.0%
acceptable bias		13.5%



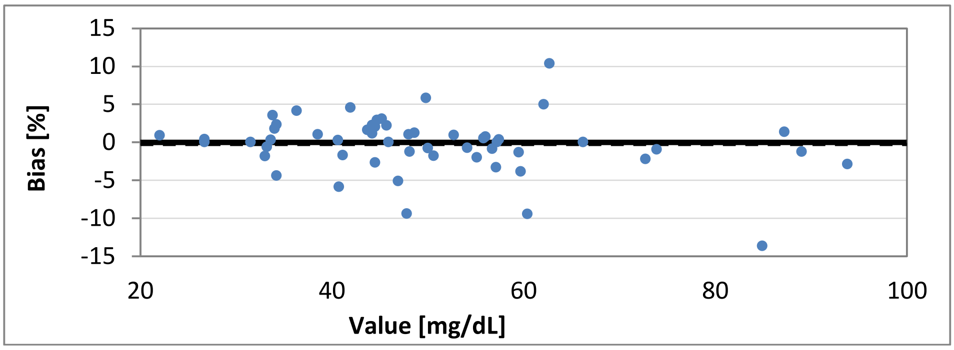


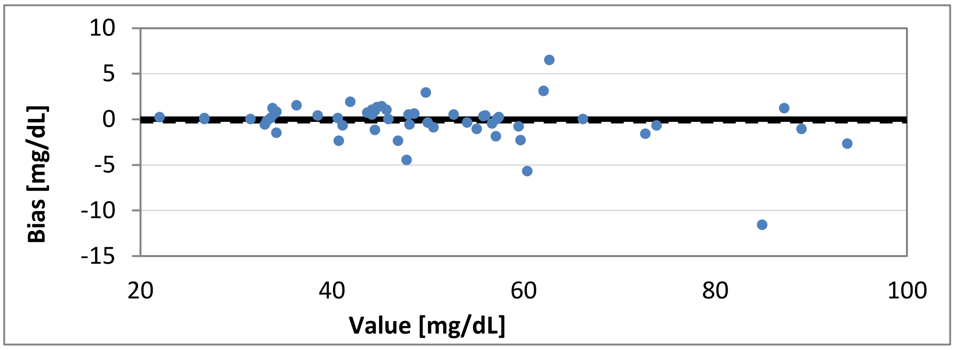
HDL (n= 55)



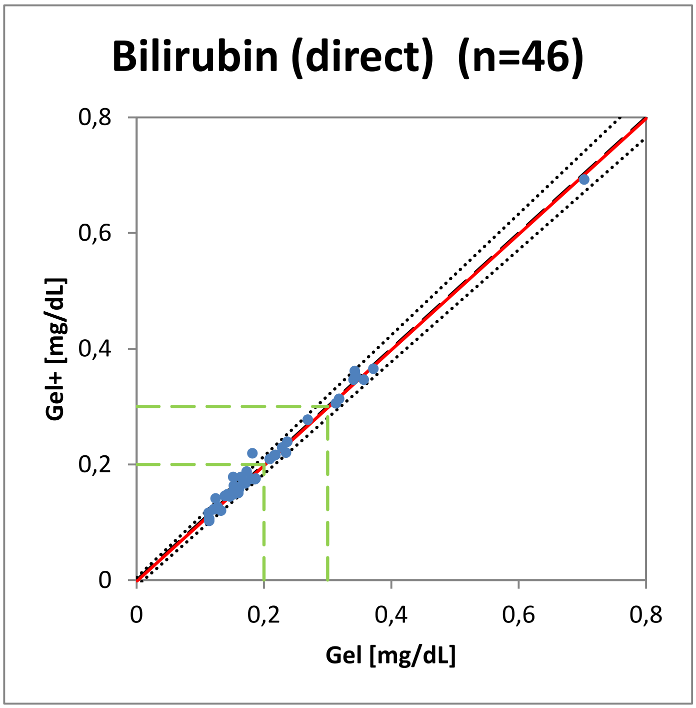
Passing-Bablok Regression	
Slope	0.9789
95 % CI	1.0077
95 % CI	0.9534
Axis	0.8558
95 % CI	2.1428
95 % CI	-0.2432

bias at relevant points		
	mg/dL	bias
Average	49.8	-0.4%
upper level	40	0.0%
lower level	60	-0.7%
acceptable bias		13.0%



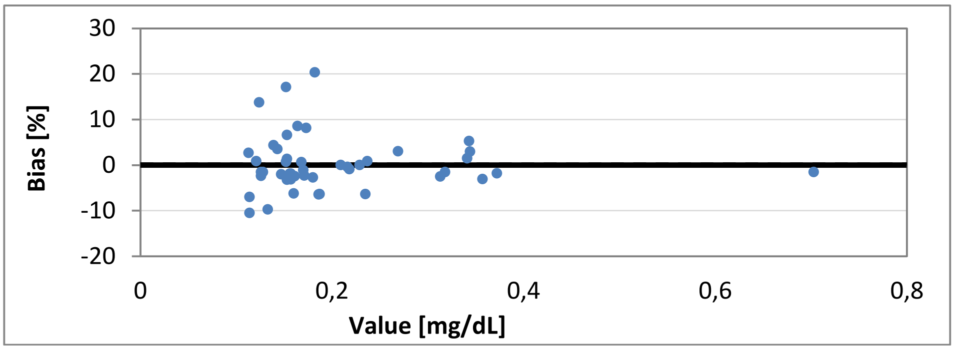


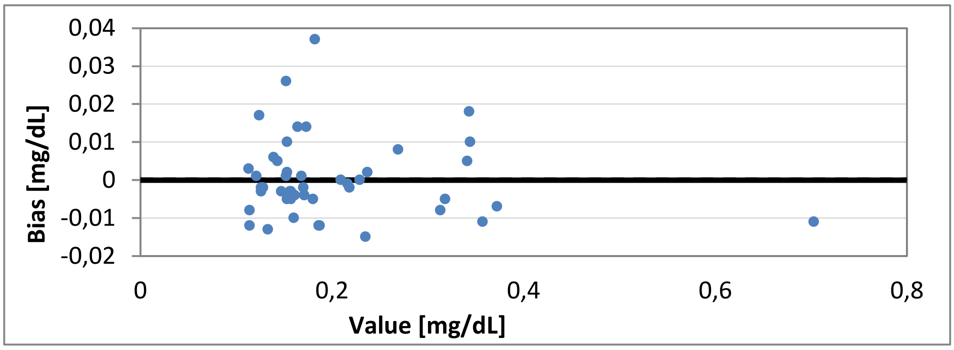
Bilirubin (direct) (n= 46)



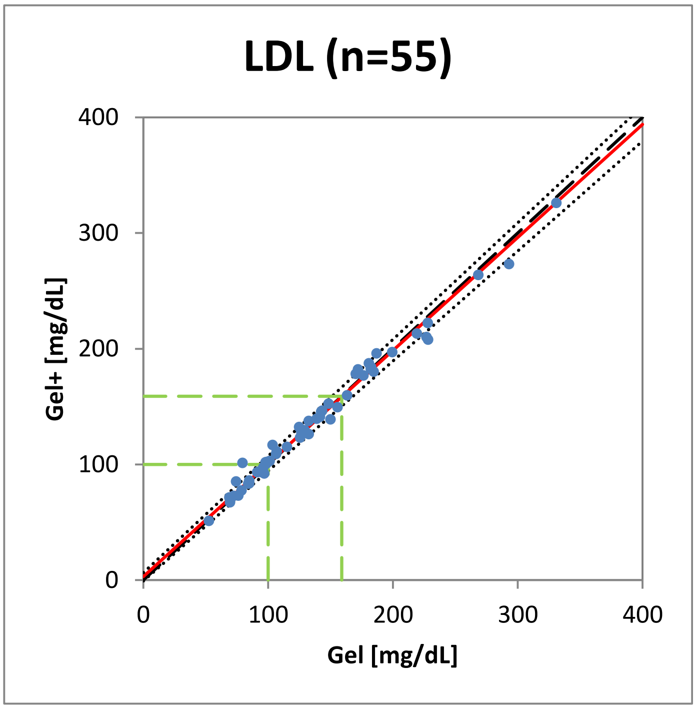
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0473
95 % CI	0.9691
Axis	-0.0020
95 % CI	0.0047
95 % CI	-0.0102

bias at relevant points		
	mg/dL	bias
Average	0.2	-1.0%
upper level	0.2	-1.0%
lower level	0.3	-0.7%
acceptable bias		22.0%



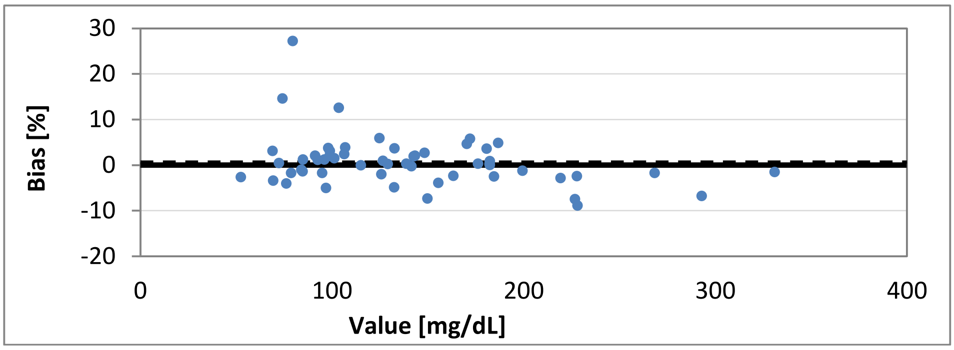


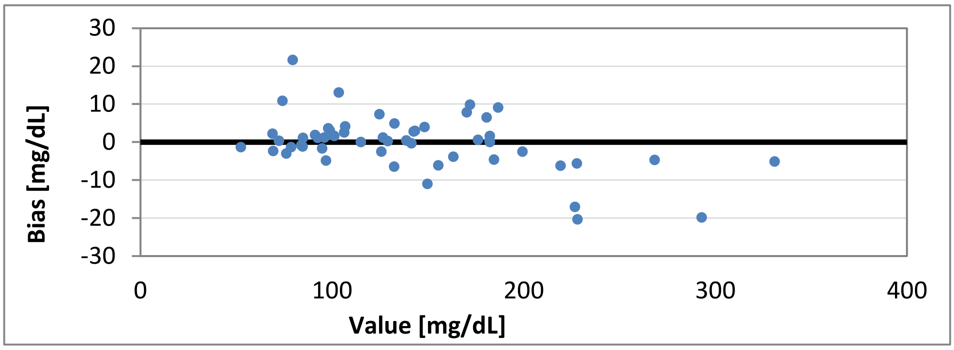
LDL (n= 55)



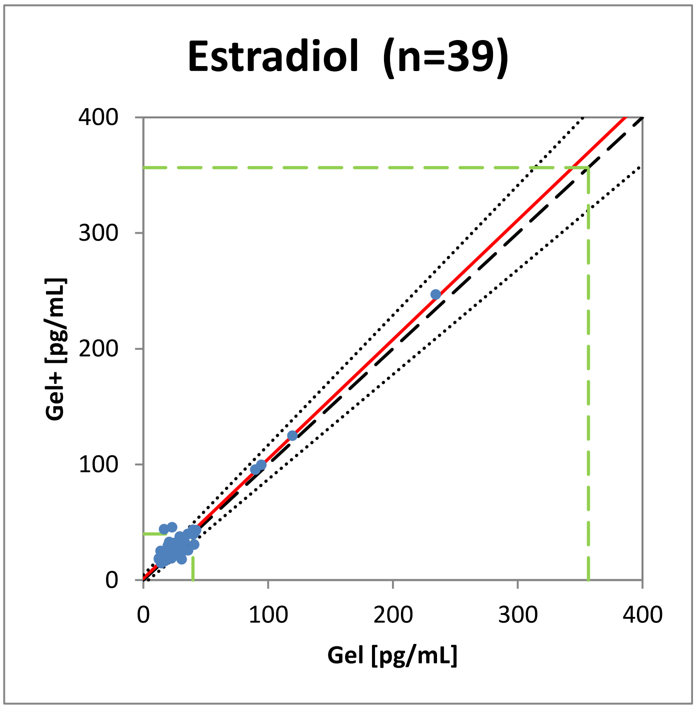
Passing-Bablok Regression	
Slope	0.9769
95 % CI	1.0081
95 % CI	0.9508
Axis	3.1838
95 % CI	6.5541
95 % CI	-0.8504

bias at relevant points		
	mg/dL	bias
Average	139.8	0.0%
upper level	100	0.9%
lower level	159	-0.3%
acceptable bias		9.0%



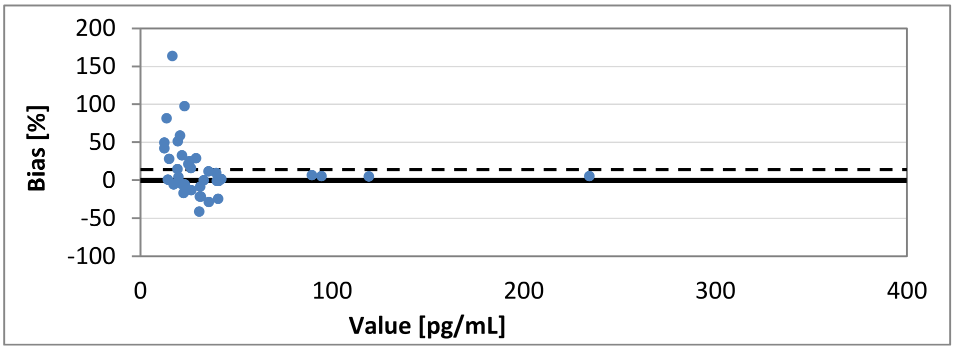


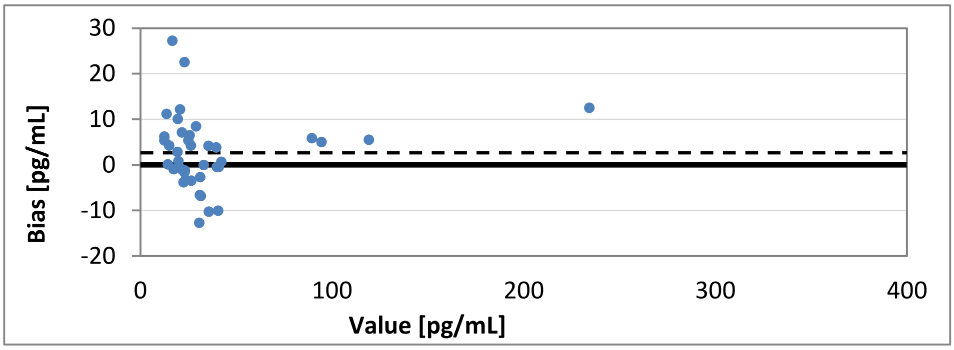
Estradiol (n= 39)



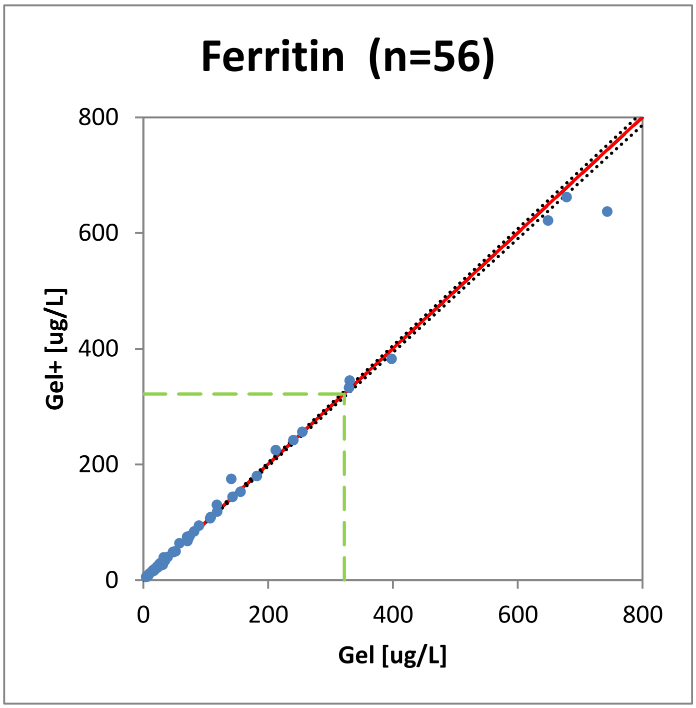
Passing-Bablok Regression	
Slope	1.0323
95 % CI	1.1225
95 % CI	0.9071
Axis	1.5569
95 % CI	4.5474
95 % CI	-3.6472

bias at relevant points		
	pg/mL	bias
Average	38.4	7.3%
upper level	39.8	7.1%
lower level	356.7	3.7%
acceptable bias		22.0%



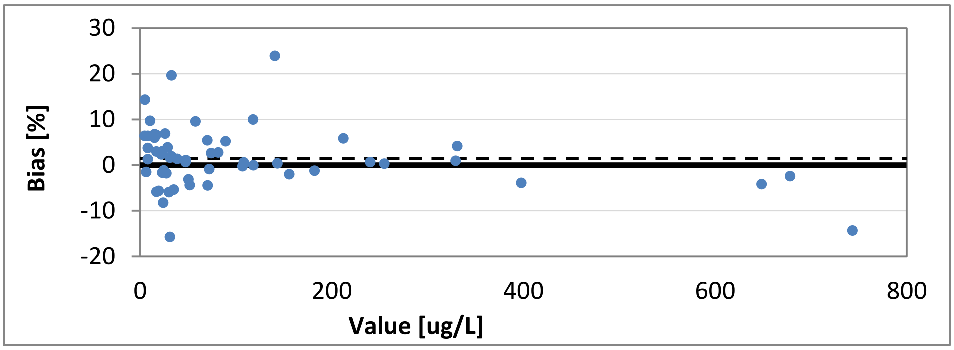


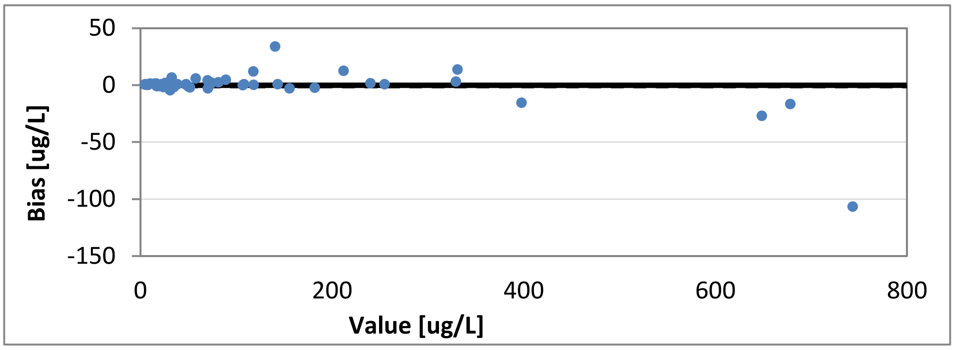
Ferritin (n= 56)



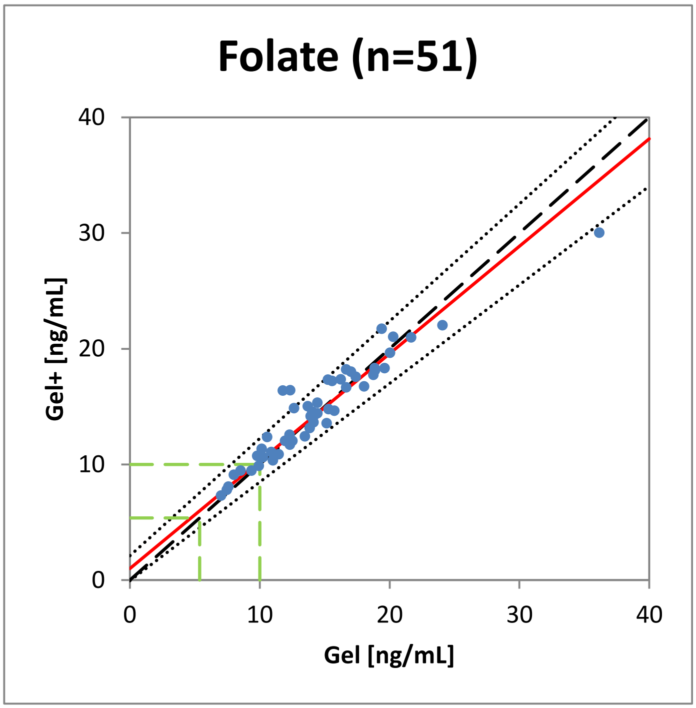
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0107
95 % CI	0.9833
Axis	0.5000
95 % CI	1.0522
95 % CI	-0.0907

bias at relevant points		
	ug/L	bias
Average	110.1	0.5%
upper level	9	5.6%
lower level	322	0.2%
acceptable bias		13.5%



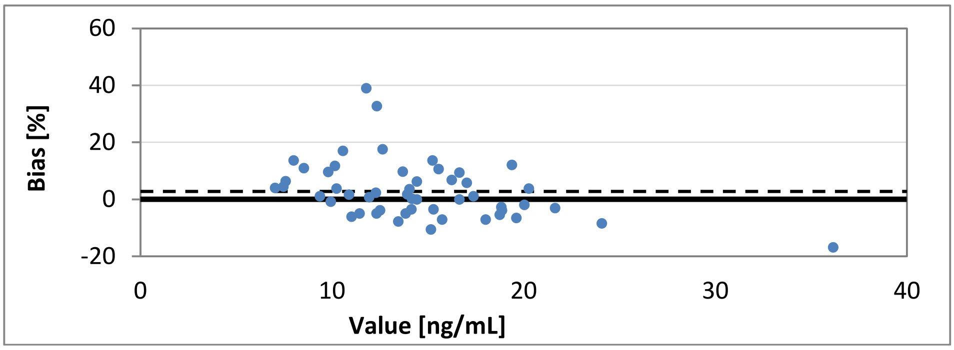


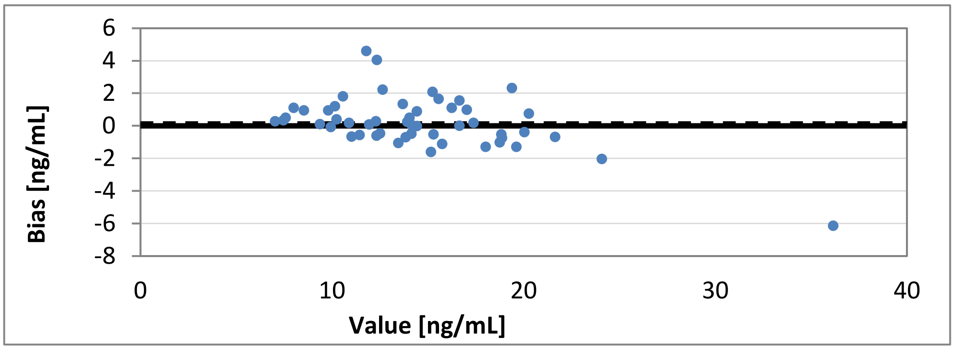
Folate (n= 51)



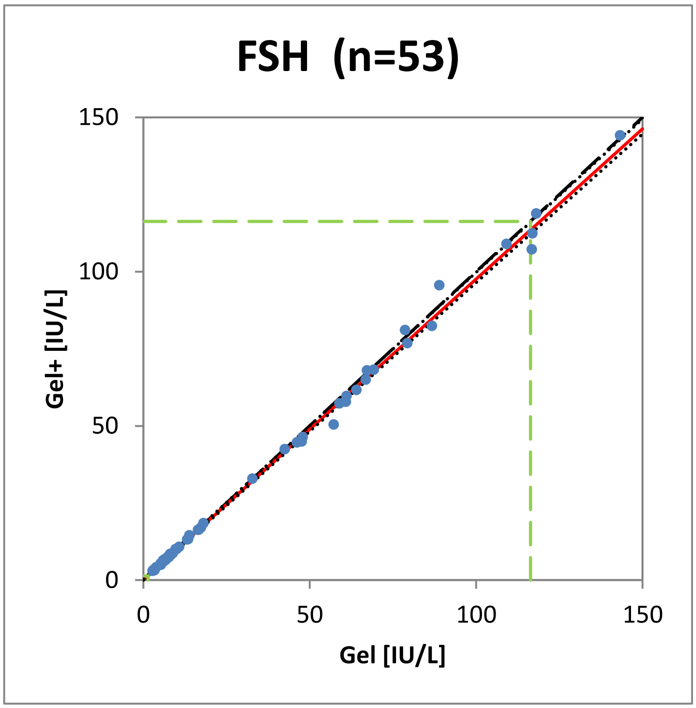
Passing-Bablok Regression	
Slope	0.9283
95 % CI	1.0138
95 % CI	0.8522
Axis	1.0133
95 % CI	2.1033
95 % CI	-0.0393

bias at relevant points		
	ng/mL	bias
Average	14.6	-0.2%
upper level	5.38	11.7%
lower level	10	3.0%
acceptable bias		25.0%



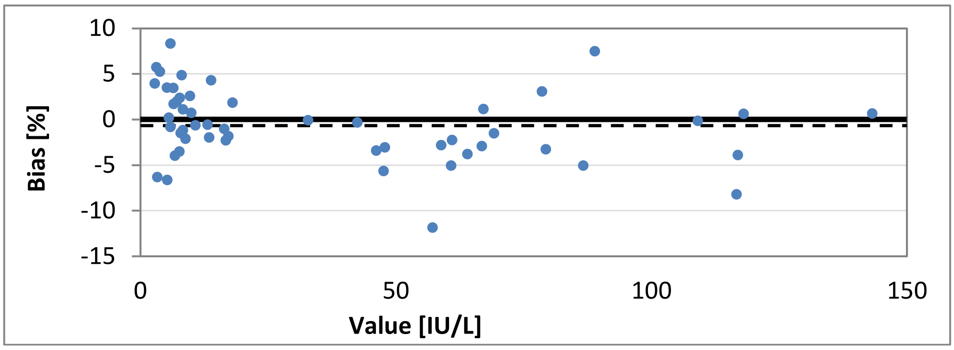


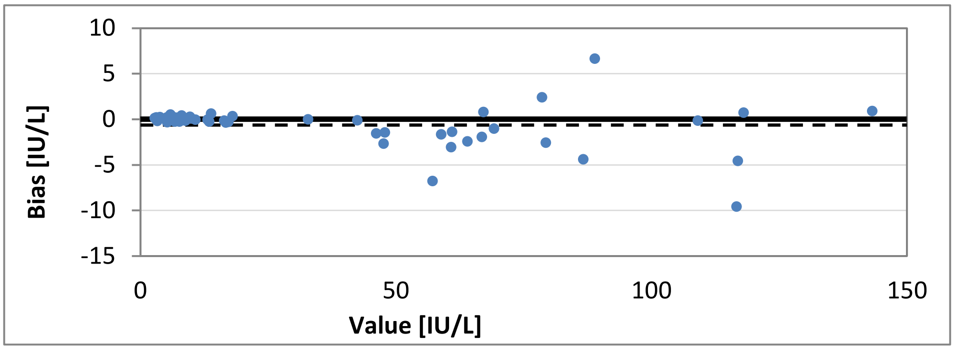
FSH (n= 53)



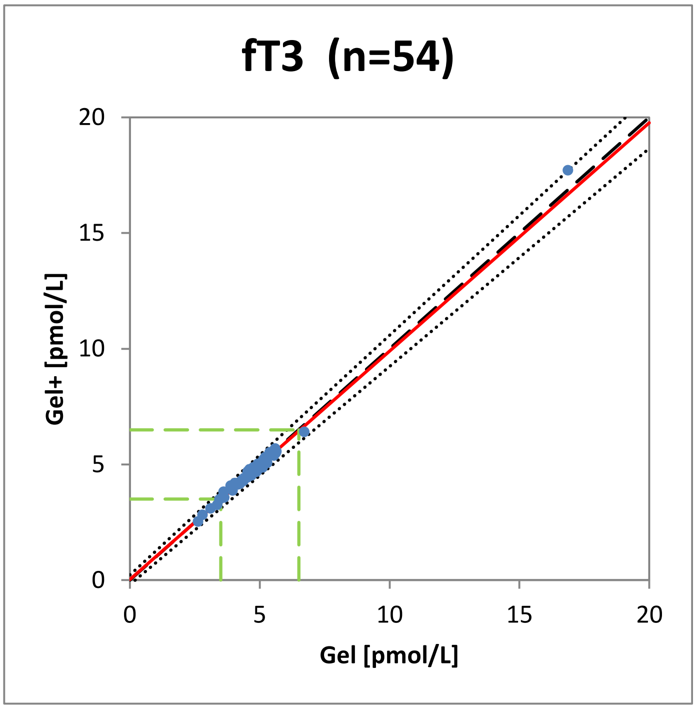
Passing-Bablok Regression	
Slope	0.9736
95 % CI	0.9944
95 % CI	0.9643
Axis	0.2147
95 % CI	0.3369
95 % CI	-0.0170

bias at relevant points		
	IU/L	bias
Average	36.1	-2.0%
upper level	1.4	12.7%
lower level	116.3	-2.5%
acceptable bias		14.0%



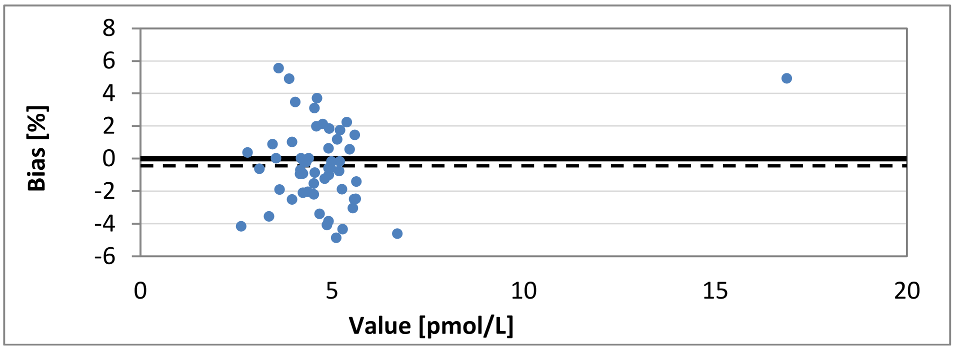


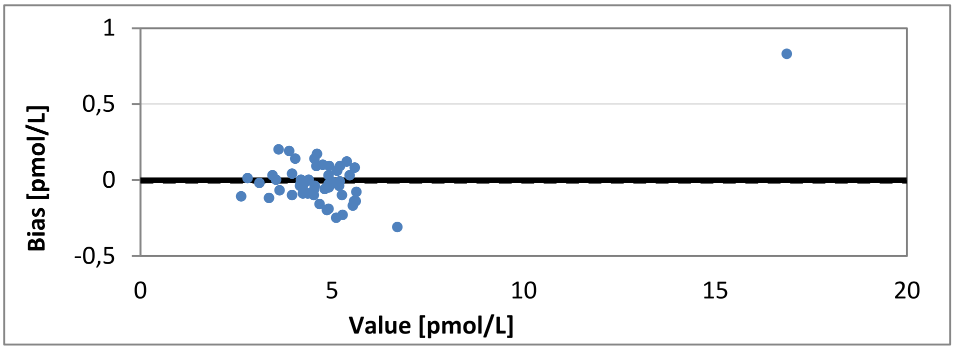
fT3 (n= 54)



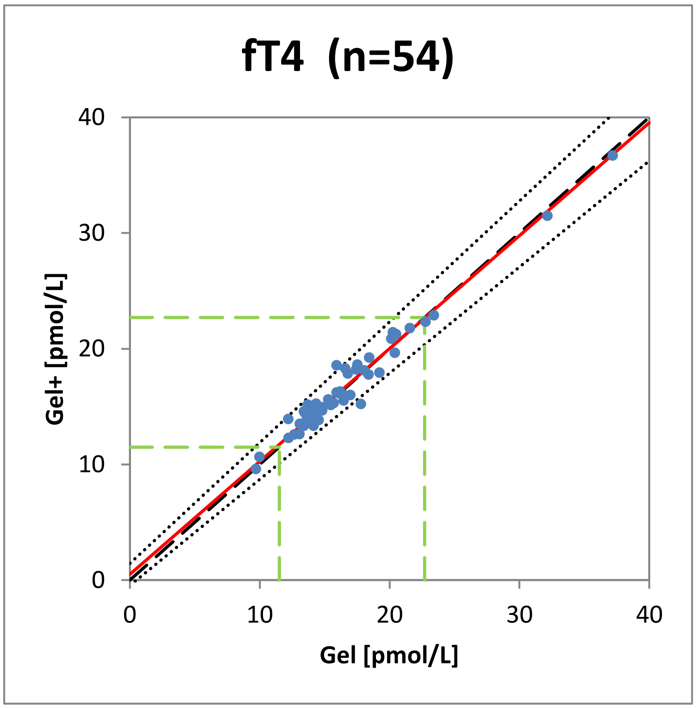
Passing-Bablok Regression	
Slope	0.9865
95 % CI	1.0354
95 % CI	0.9423
Axis	0.0332
95 % CI	0.2314
95 % CI	-0.1888

bias at relevant points		
	pmol/L	bias
Average	4.8	-0.7%
upper level	3.5	-0.4%
lower level	6.5	-0.8%
acceptable bias		13.0%



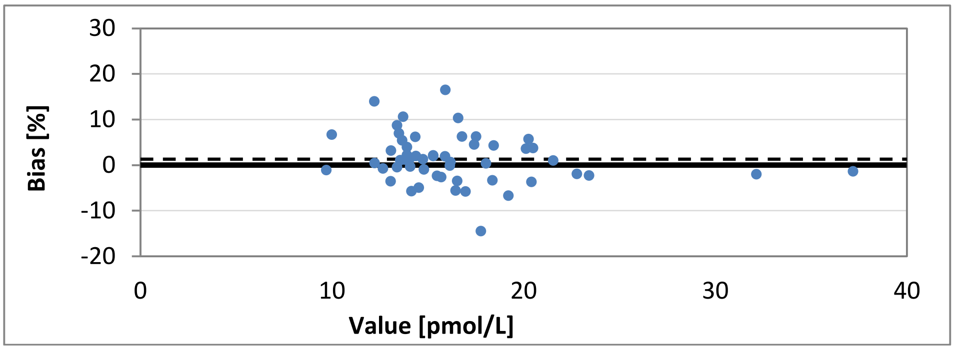


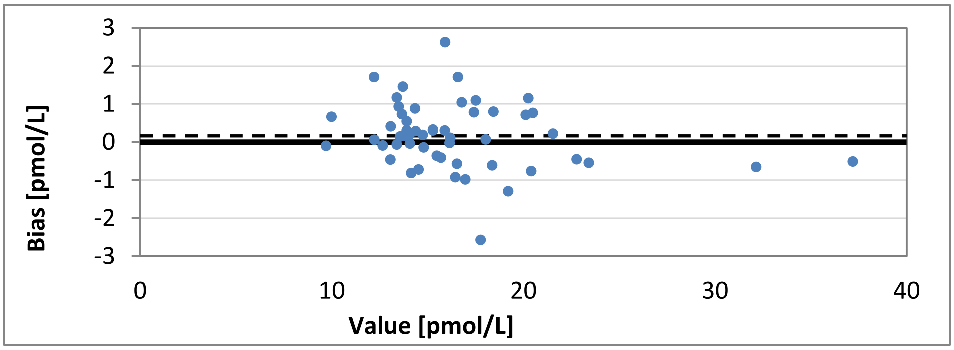
fT4 (n= 54)



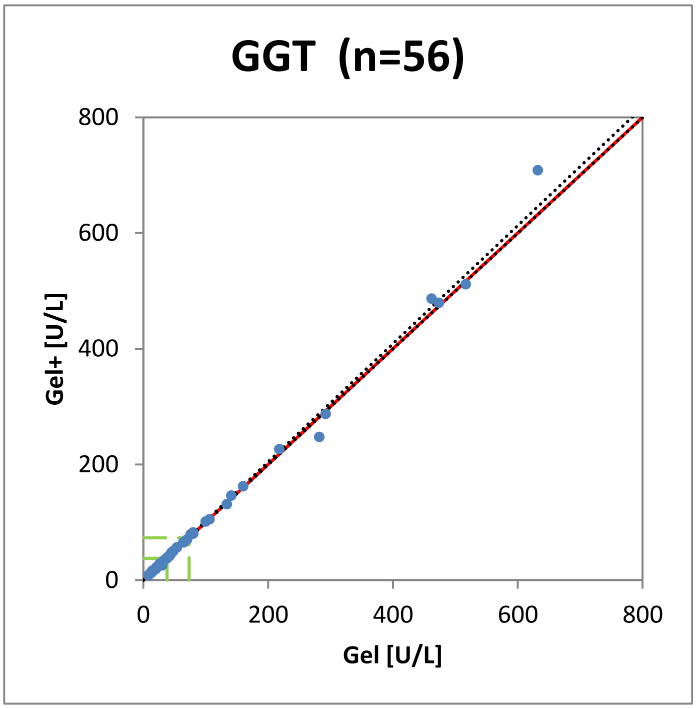
Passing-Bablok Regression	
Slope	0.9757
95 % CI	1.0444
95 % CI	0.9179
Axis	0.5033
95 % CI	1.4352
95 % CI	-0.4691

bias at relevant points		
	pmol/L	bias
Average	16.5	0.6%
upper level	11.5	1.9%
lower level	22.7	-0.2%
acceptable bias		13.0%



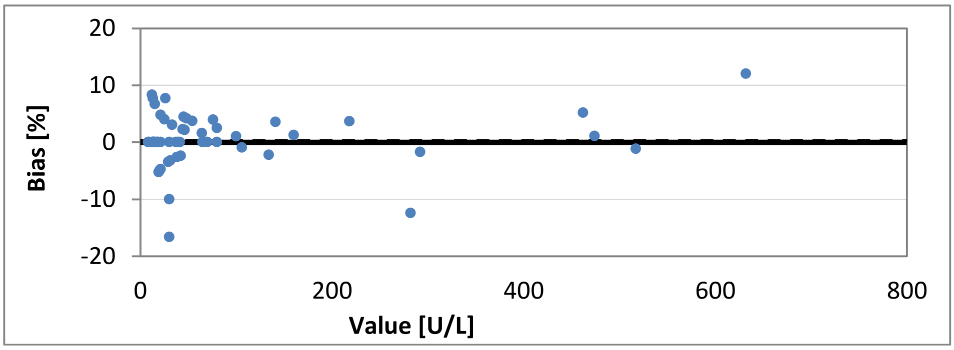


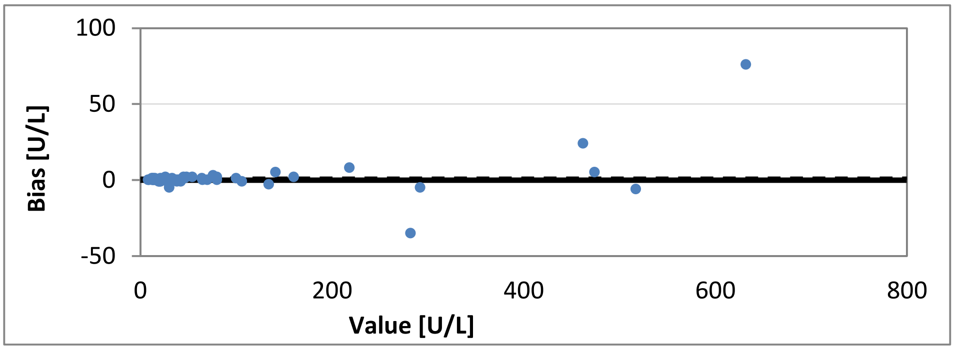
GGT (n= 56)



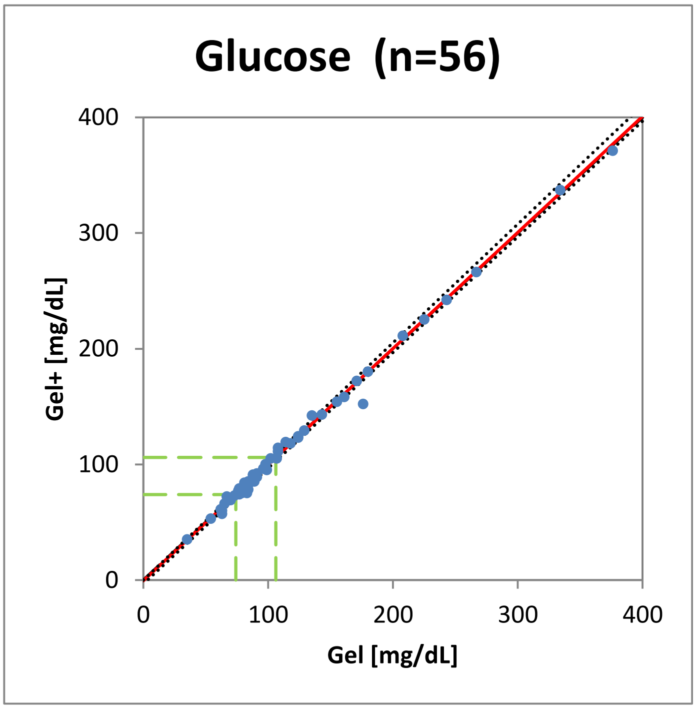
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0217
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	-0.3913

bias at relevant points		
	U/L	bias
Average	88.8	0.0%
upper level	38	0.0%
lower level	73	0.0%
acceptable bias		11.5%



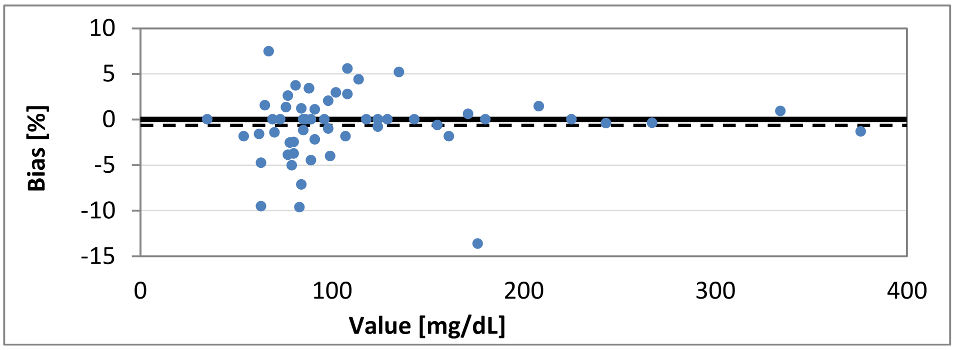


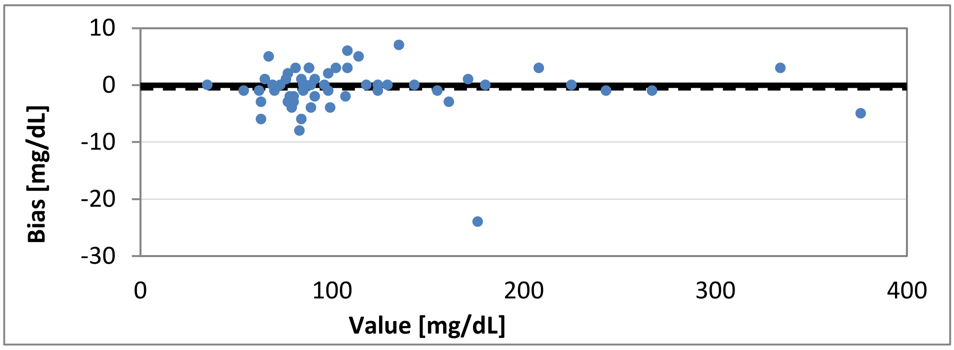
Glucose (n= 56)



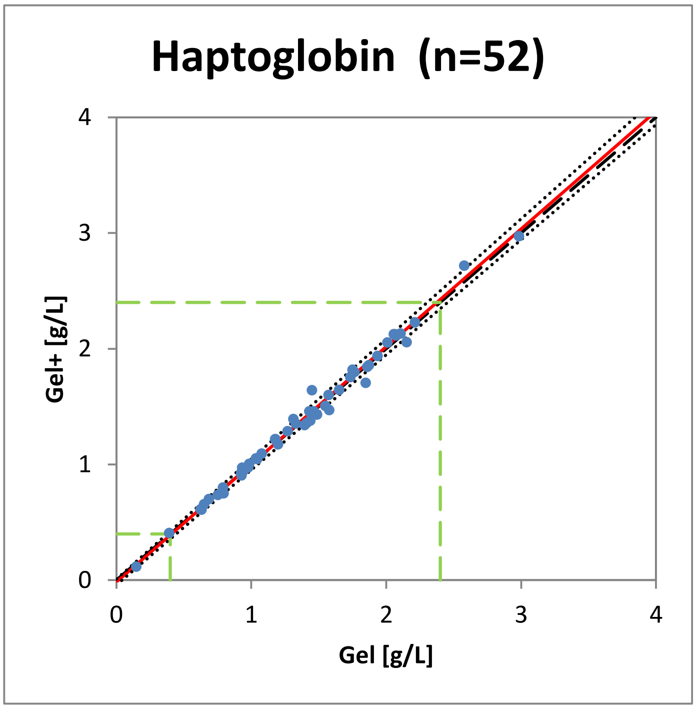
Passing-Bablok Regression	
Slope	1.0037
95 % CI	1.0256
95 % CI	1.0000
Axis	-0.4975
95 % CI	0.0000
95 % CI	-3.1795

bias at relevant points		
	mg/dL	bias
Average	115.6	-0.1%
upper level	74	-0.3%
lower level	106	-0.1%
acceptable bias		11.0%



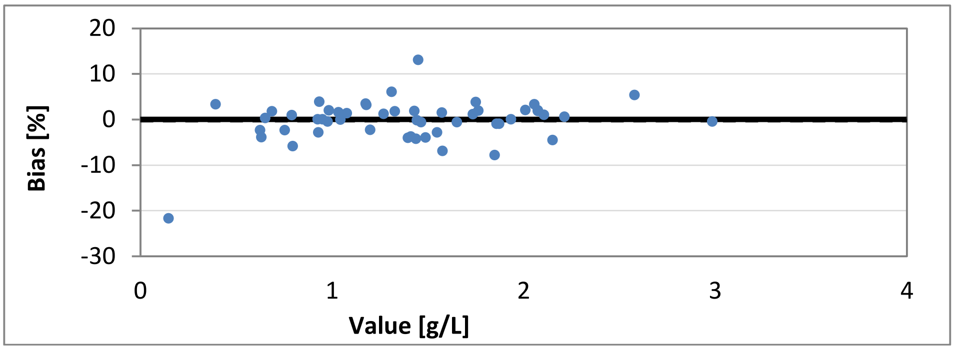


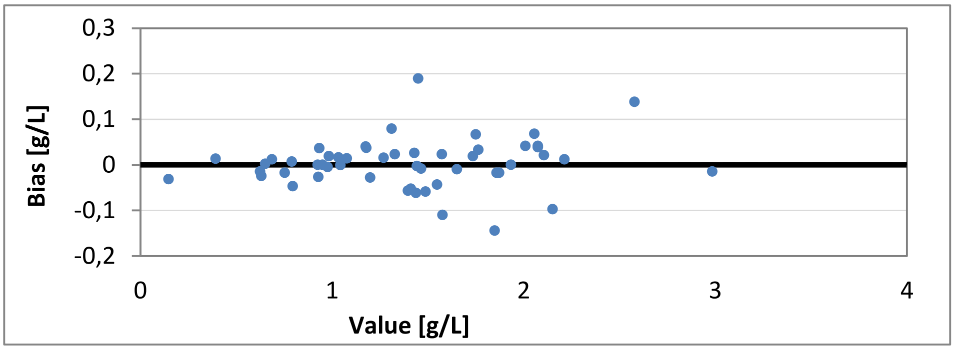
Haptoglobin (n= 52)



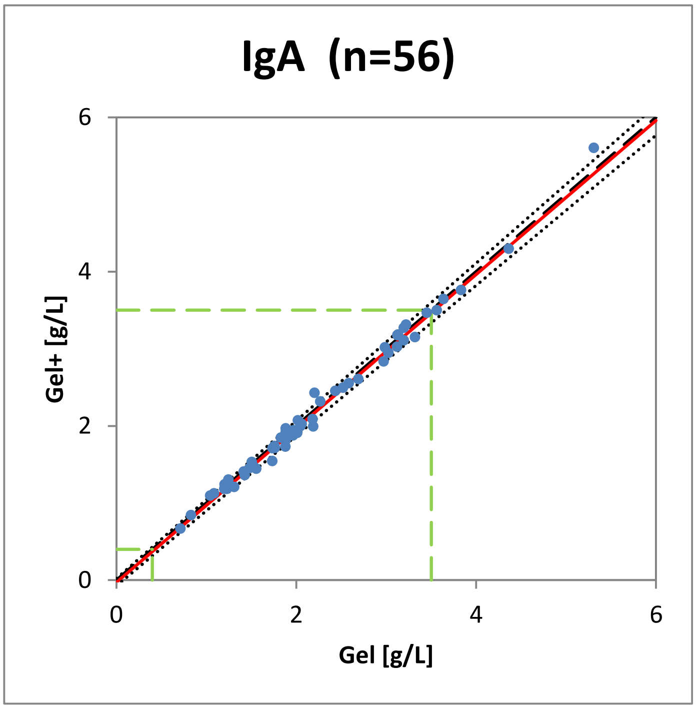
Passing-Bablok Regression	
Slope	1.0174
95 % CI	1.0379
95 % CI	0.9939
Axis	-0.0164
95 % CI	0.0089
95 % CI	-0.0396

bias at relevant points		
	g/L	bias
Average	1.4	0.6%
upper level	0.4	-2.3%
lower level	2.4	1.1%
acceptable bias		20.0%



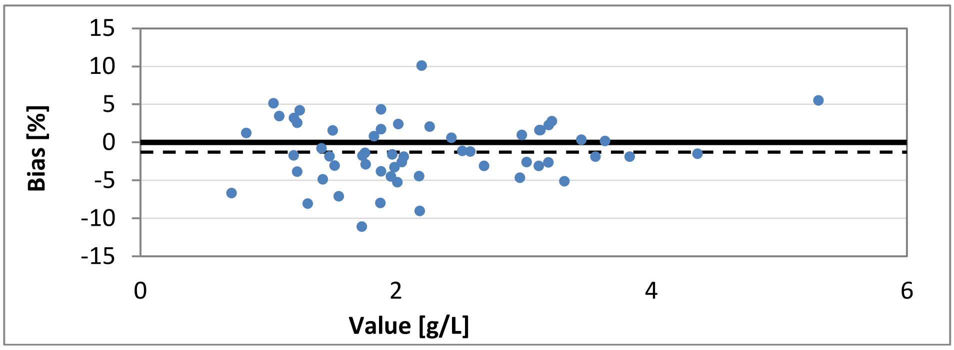


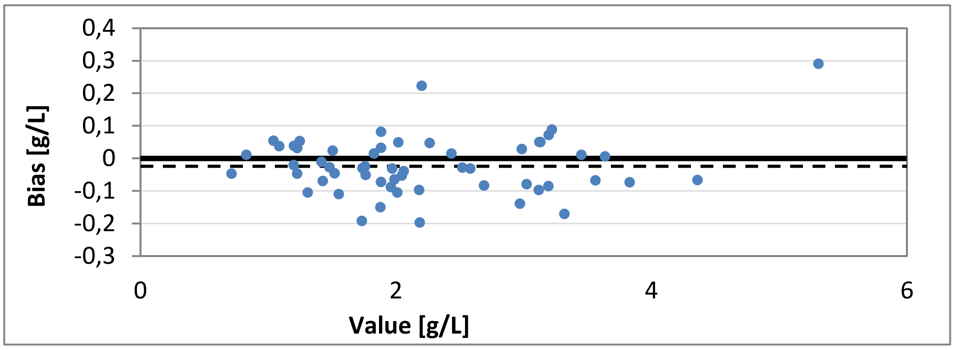
IgA (n= 56)



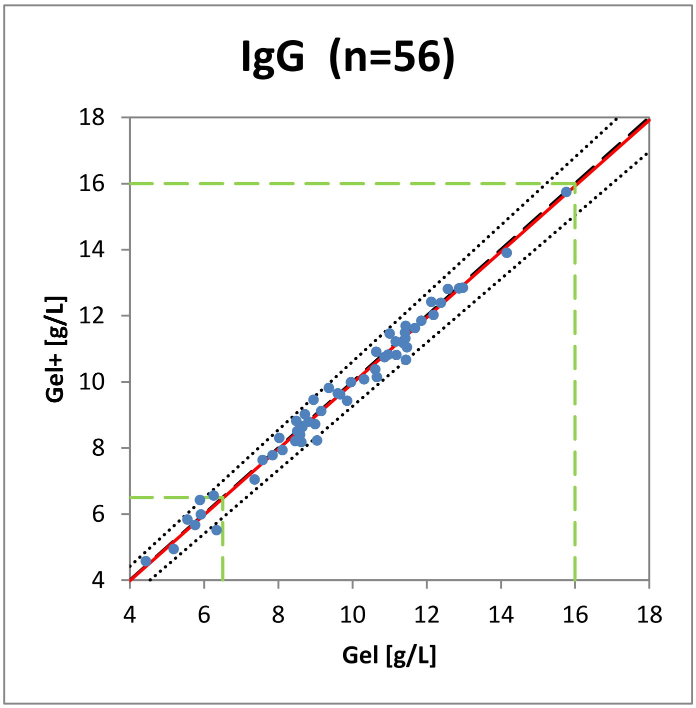
Passing-Bablok Regression	
Slope	0.9981
95 % CI	1.0222
95 % CI	0.9742
Axis	-0.0274
95 % CI	0.0221
95 % CI	-0.0755

bias at relevant points		
	g/L	bias
Average	2.2	-1.4%
upper level	0.4	-7.0%
lower level	3.5	-1.0%
acceptable bias		12.0%



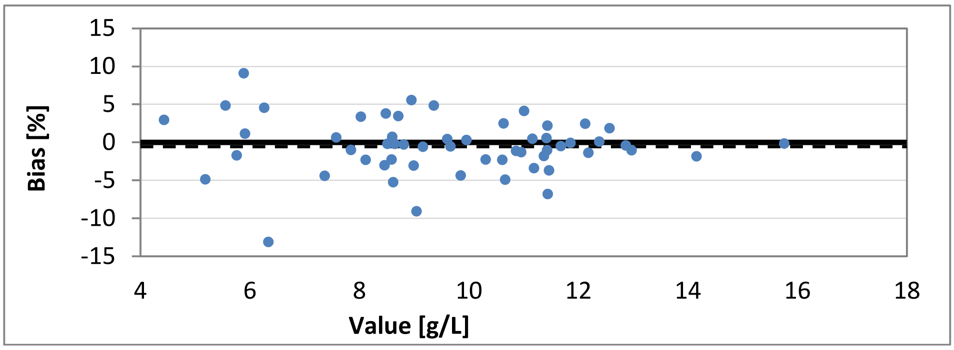


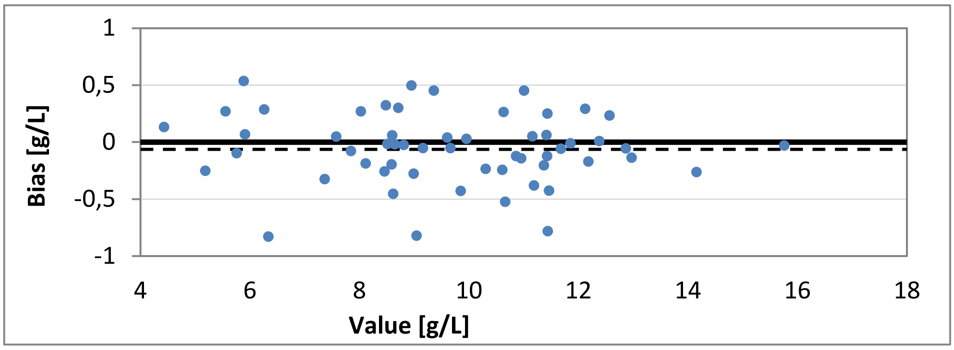
IgG (n= 56)



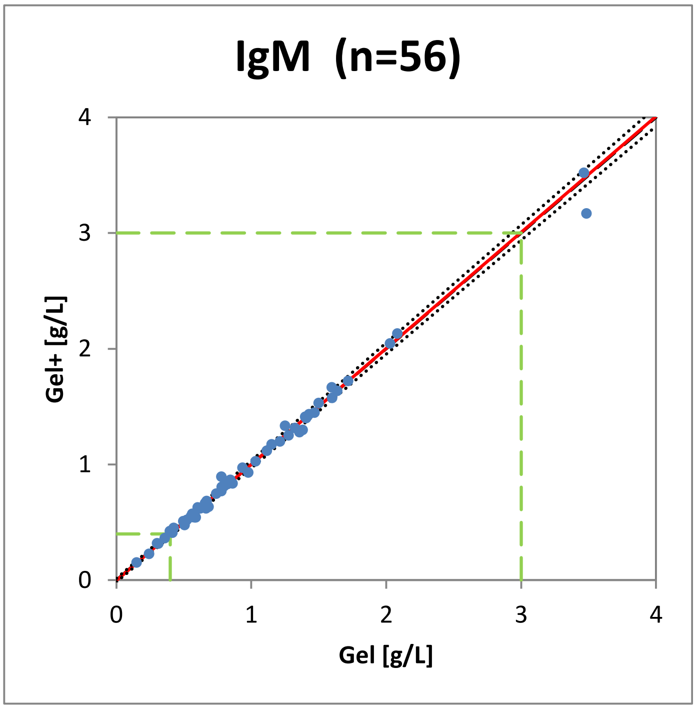
Passing-Bablok Regression	
Slope	0.9954
95 % CI	1.0319
95 % CI	0.9635
Axis	-0.0024
95 % CI	0.2929
95 % CI	-0.3758

bias at relevant points		
	g/L	bias
Average	9.6	-0.5%
upper level	6.5	-0.5%
lower level	16	-0.5%
acceptable bias		10.0%



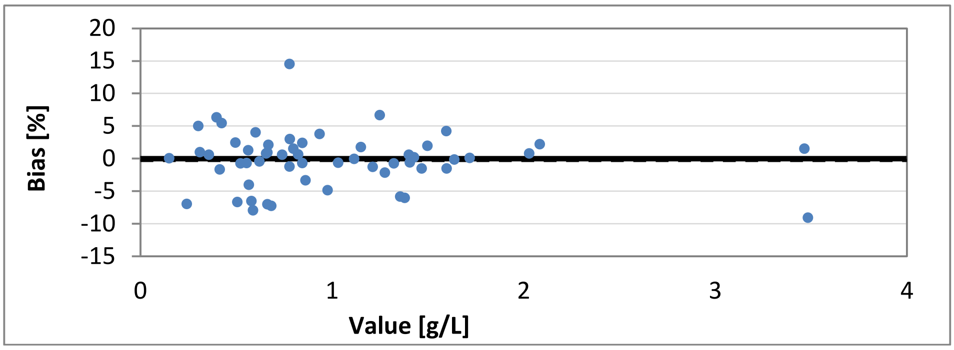


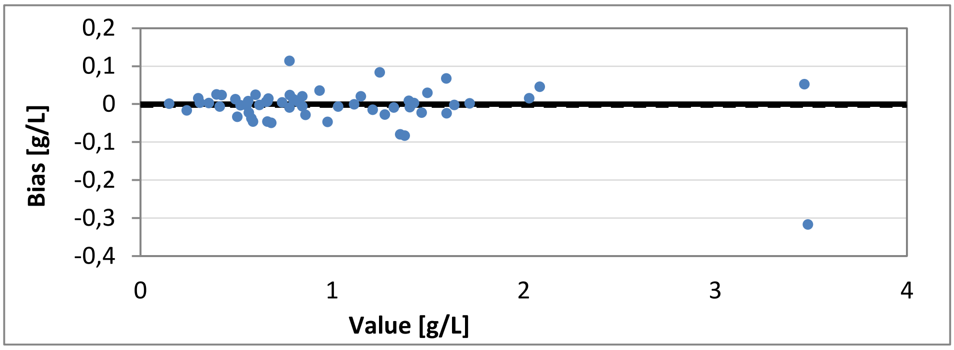
IgM (n= 56)



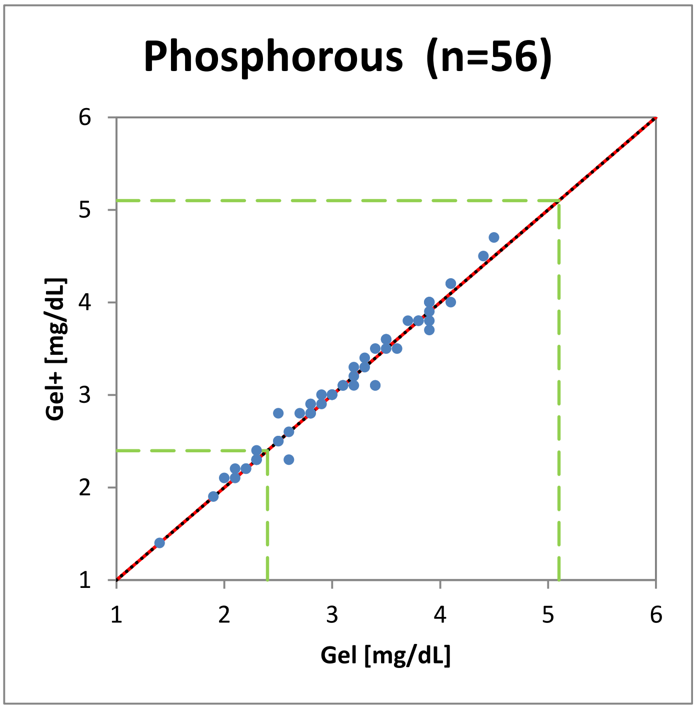
Passing-Bablok Regression	
Slope	1.0030
95 % CI	1.0190
95 % CI	0.9845
Axis	-0.0032
95 % CI	0.0140
95 % CI	-0.0149

bias at relevant points		
	g/L	bias
Average	1.0	0.0%
upper level	0.4	-0.5%
lower level	3	0.2%
acceptable bias		13.0%



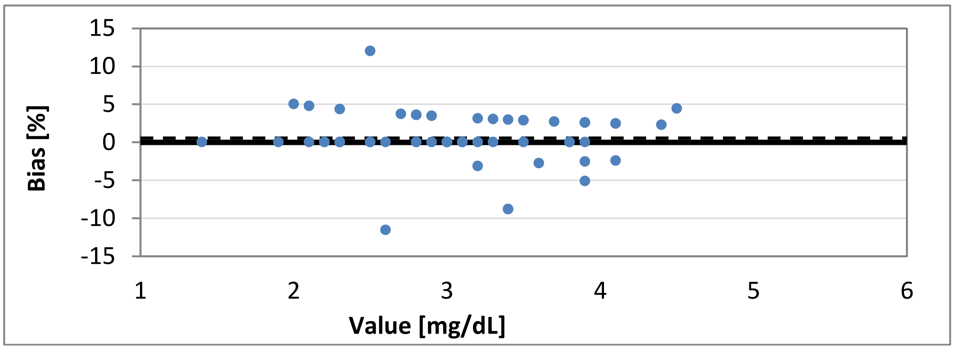


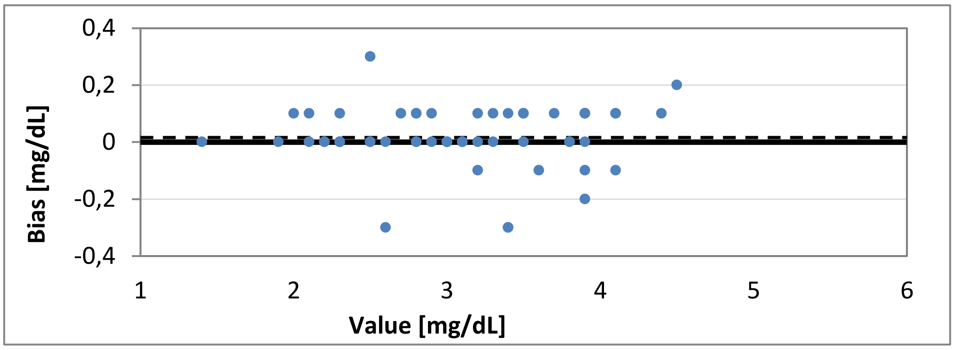
Phosphorous (n= 56)



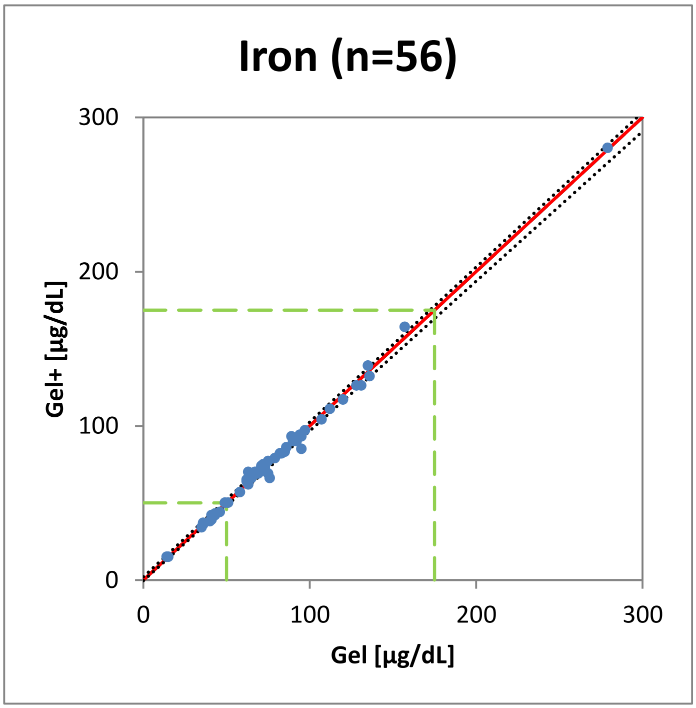
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0000
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	0.0000

bias at relevant points		
	mg/dL	bias
Average	3.1	0.0%
upper level	2.4	0.0%
lower level	5.1	0.0%
acceptable bias		9.0%



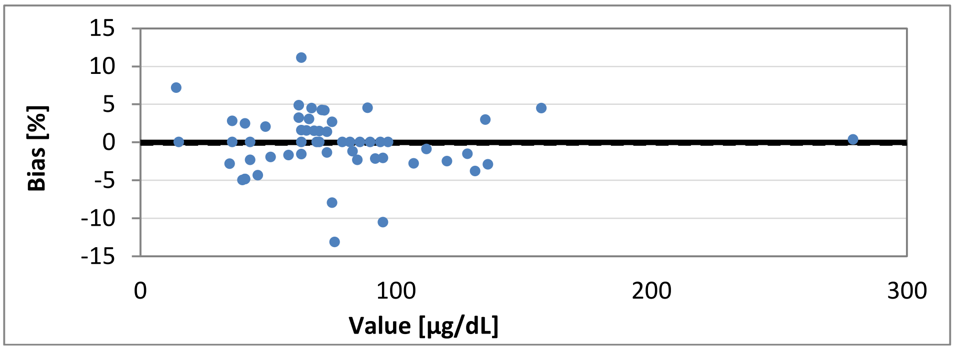


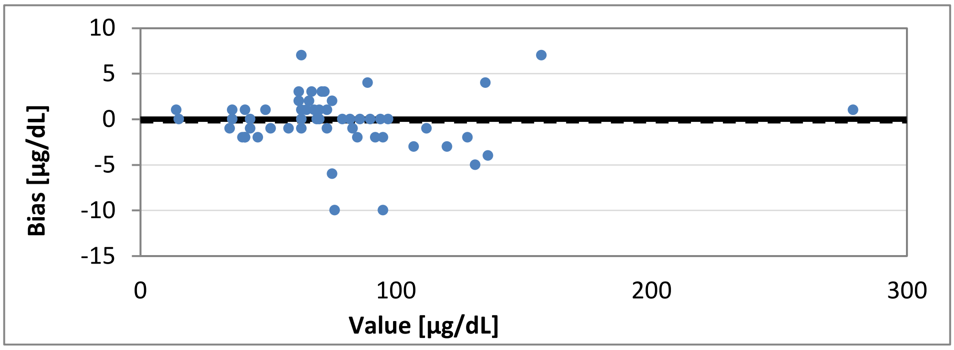
Iron (n= 56)



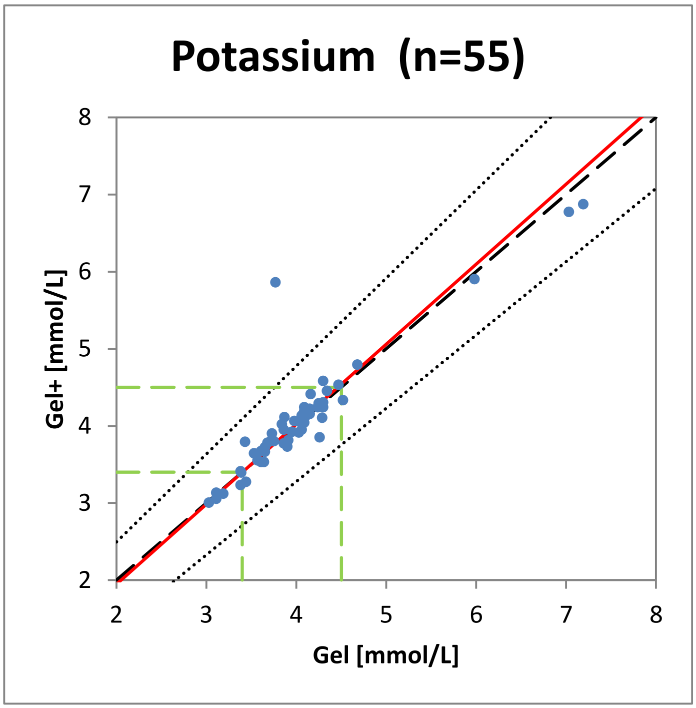
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0046
95 % CI	0.9706
Axis	0.0000
95 % CI	2.0441
95 % CI	-0.3727

bias at relevant points		
	µg/dL	bias
Average	77.1	0.0%
upper level	50	0.0%
lower level	175	0.0%
acceptable bias		30.7%



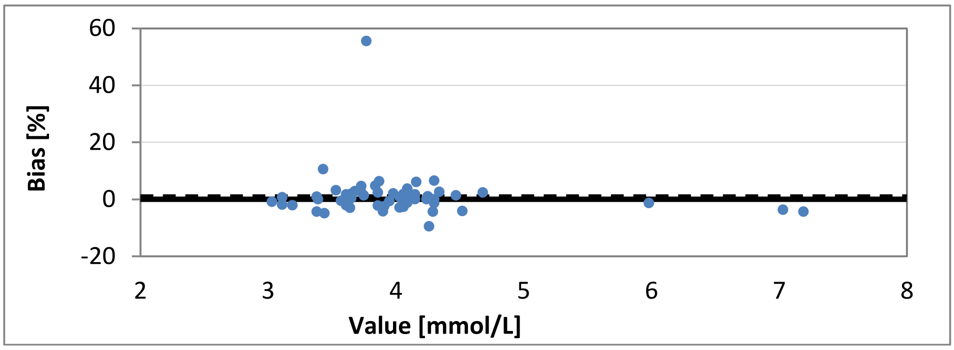


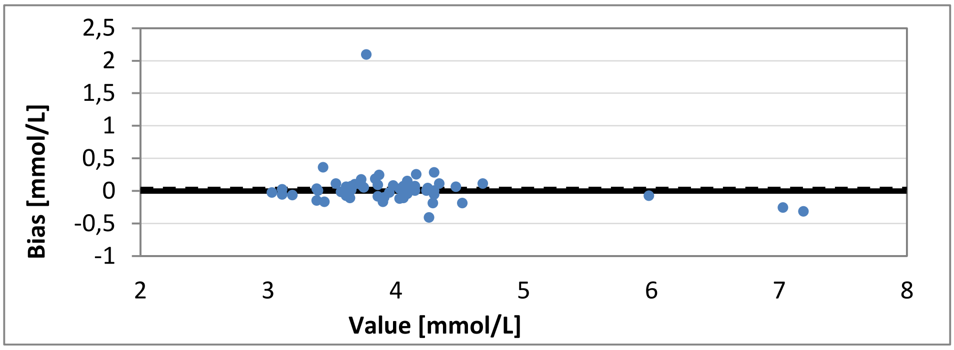
Potassium (n= 55)



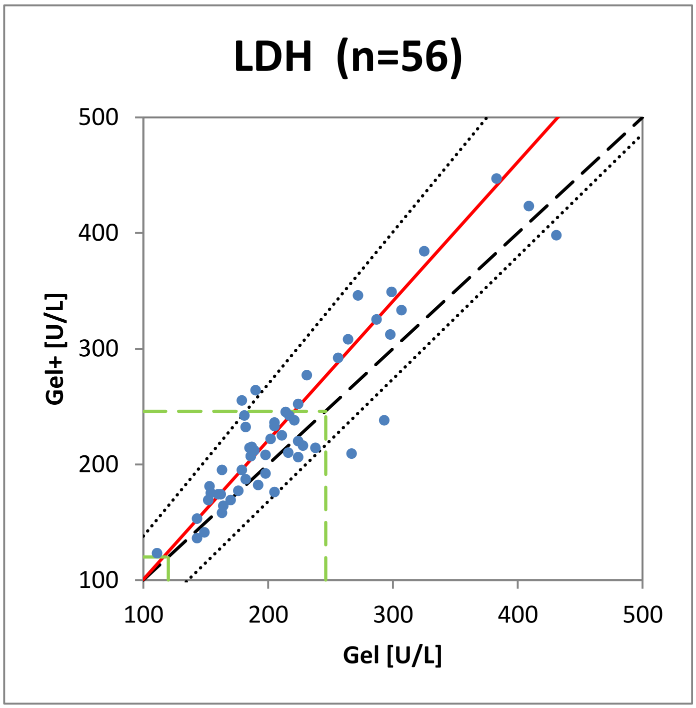
Passing-Bablok Regression	
Slope	1.0370
95 % CI	1.1404
95 % CI	0.9500
Axis	-0.1256
95 % CI	0.2150
95 % CI	-0.5211

bias at relevant points		
	mmol/L	bias
Average	4.1	0.6%
upper level	3.4	0.0%
lower level	4.5	0.9%
acceptable bias		4.5%



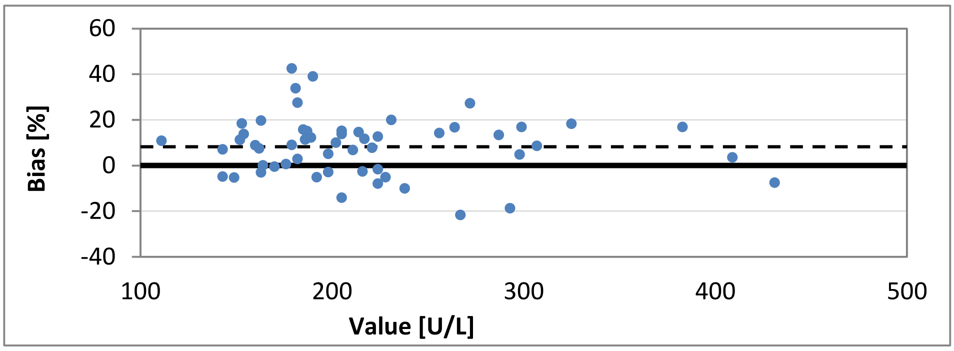


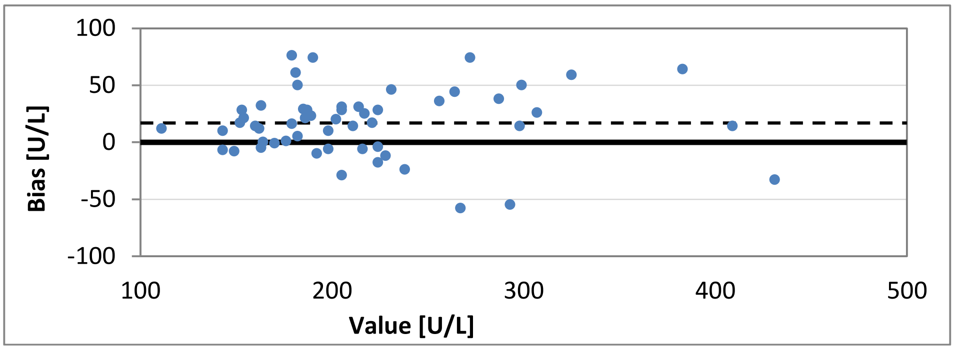
LDH (n= 56)



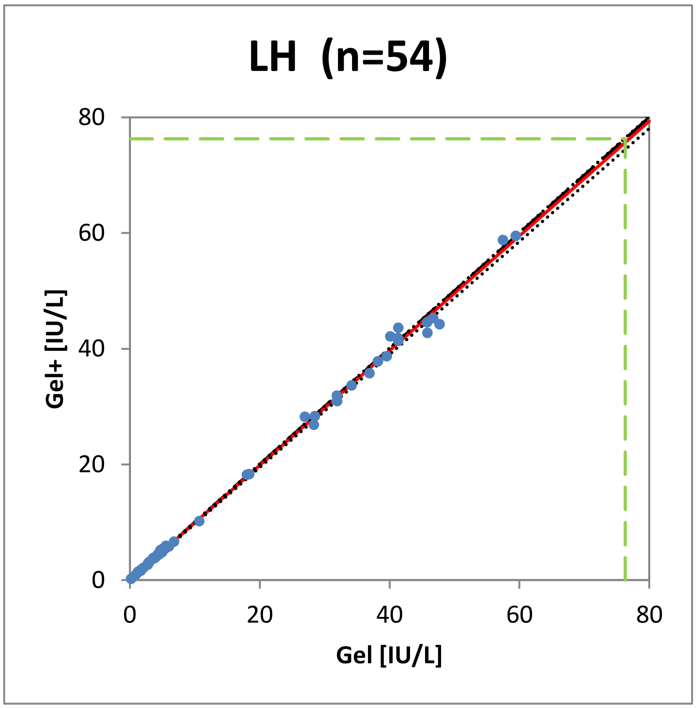
Passing-Bablok Regression	
Slope	1.2027
95 % CI	1.3143
95 % CI	1.0588
Axis	-19.5811
95 % CI	6.7059
95 % CI	-43.7286

bias at relevant points		
	U/L	bias
Average	225.1	11.6%
upper level	120	4.0%
lower level	246	12.3%
acceptable bias		9.0%



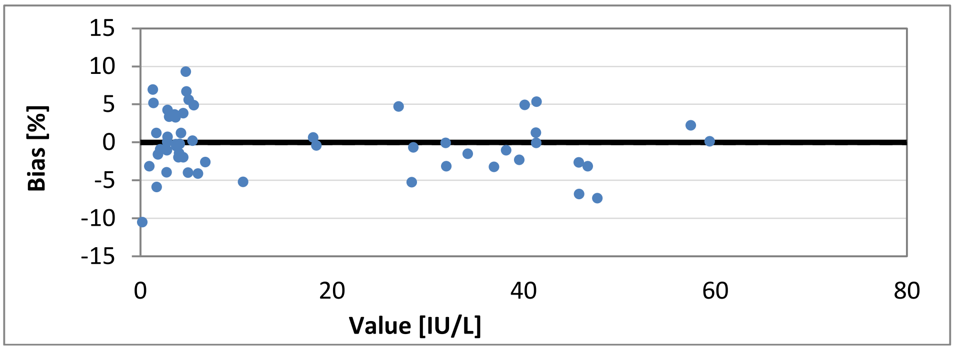


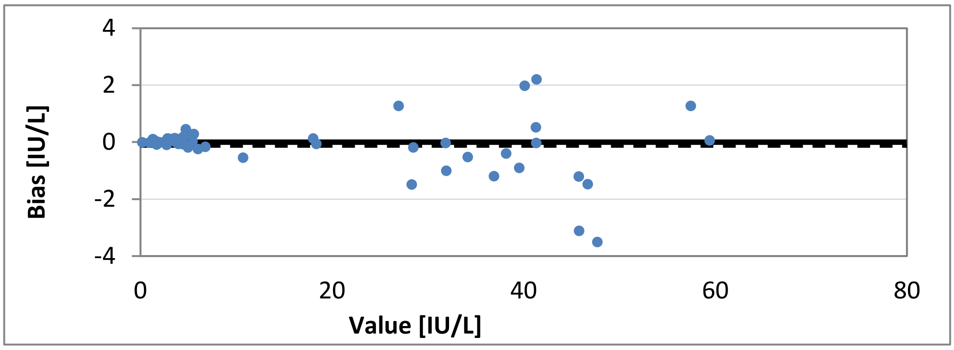
LH (n= 54)



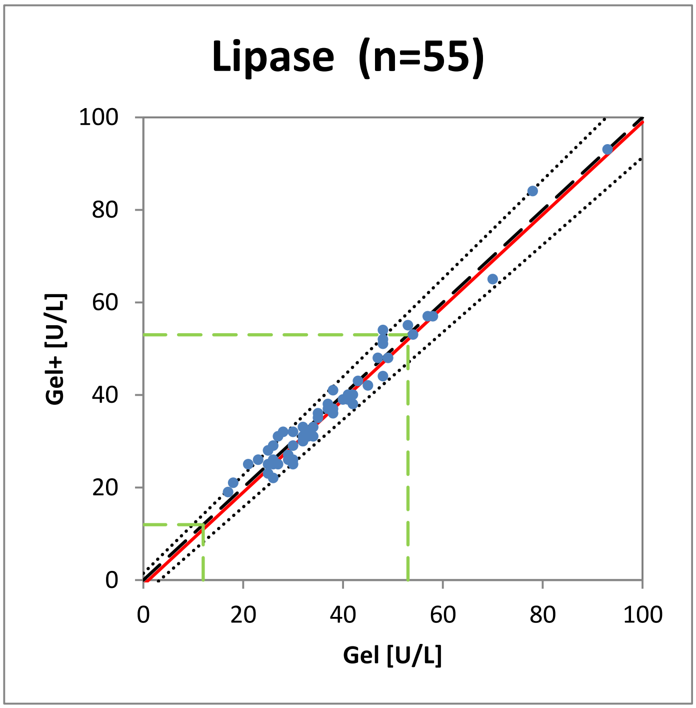
Passing-Bablok Regression	
Slope	0.9915
95 % CI	1.0014
95 % CI	0.9763
Axis	0.0244
95 % CI	0.0870
95 % CI	-0.0283

bias at relevant points		
	IU/L	bias
Average	17.0	-0.7%
upper level	0.5	4.0%
lower level	76.3	-0.8%
acceptable bias		15.0%



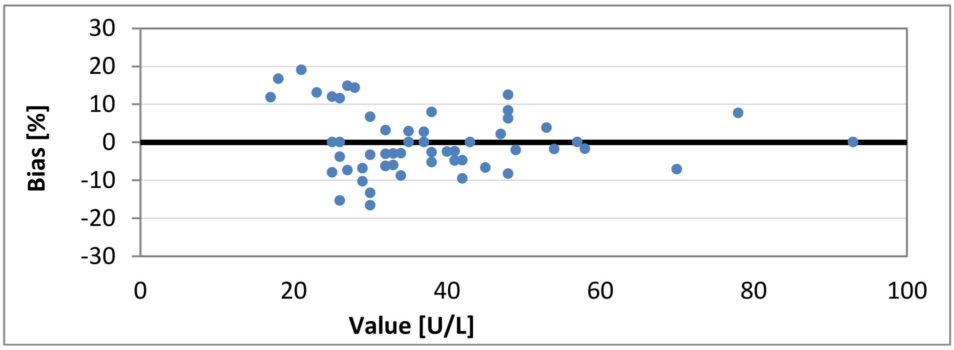


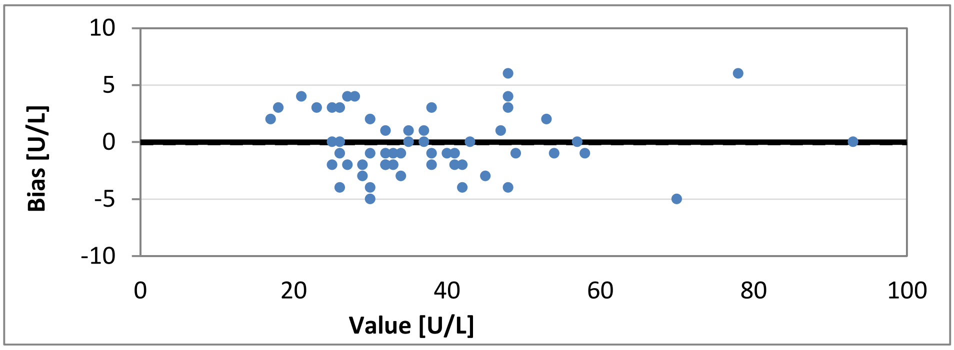
Lipase (n= 55)



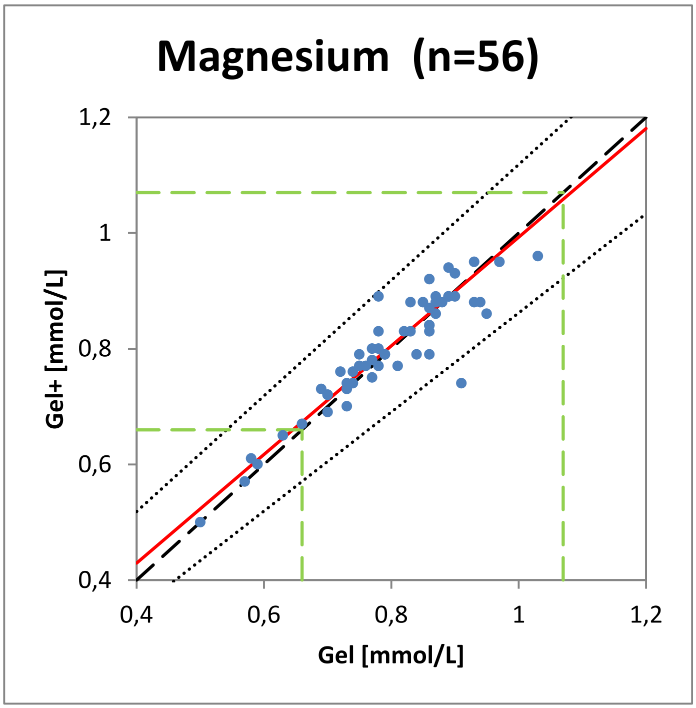
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0625
95 % CI	0.9444
Axis	-1.0000
95 % CI	1.4444
95 % CI	-3.0625

bias at relevant points		
	U/L	bias
Average	37.8	-2.6%
upper level	12	-8.3%
lower level	53	-1.9%
acceptable bias		11.0%



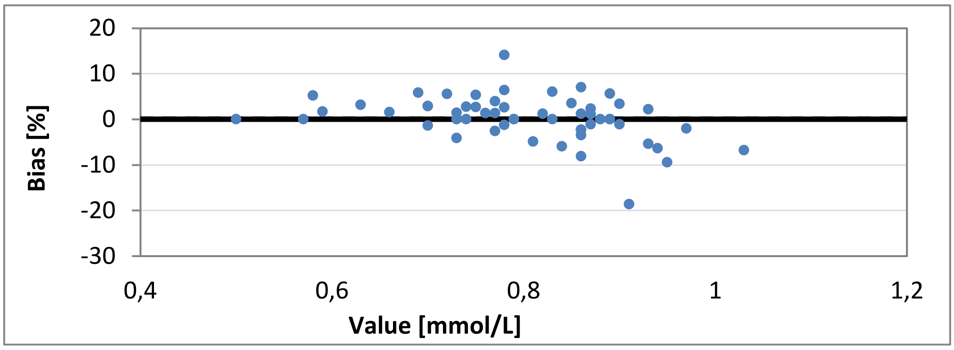


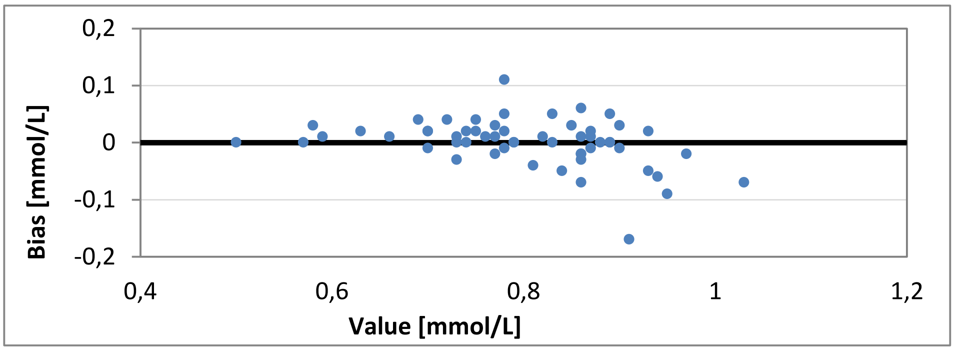
Magnesium (n= 56)



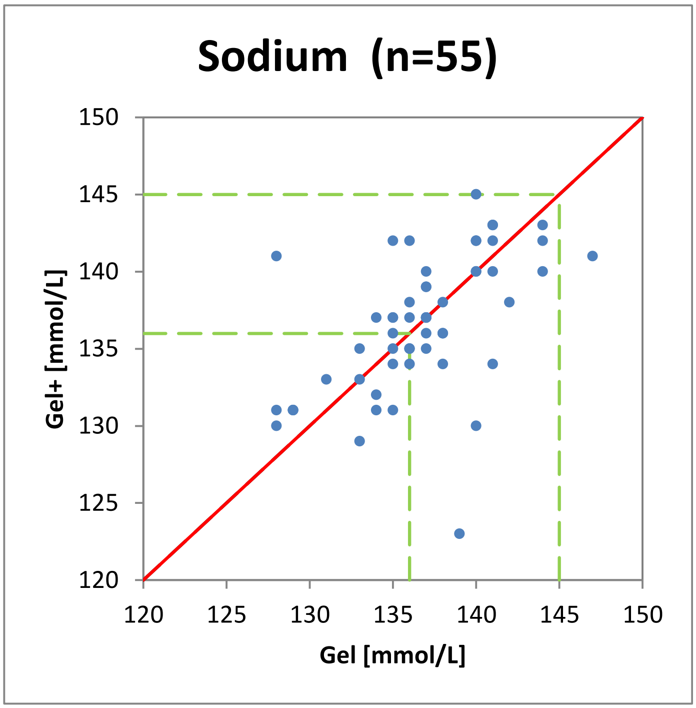
Passing-Bablok Regression	
Slope	0.9393
95 % CI	1.0000
95 % CI	0.8571
Axis	0.0537
95 % CI	0.1186
95 % CI	0.0050

bias at relevant points		
	mmol/L	bias
Average	0.8	0.7%
upper level	0.66	2.1%
lower level	1.07	-1.0%
acceptable bias		7.5%



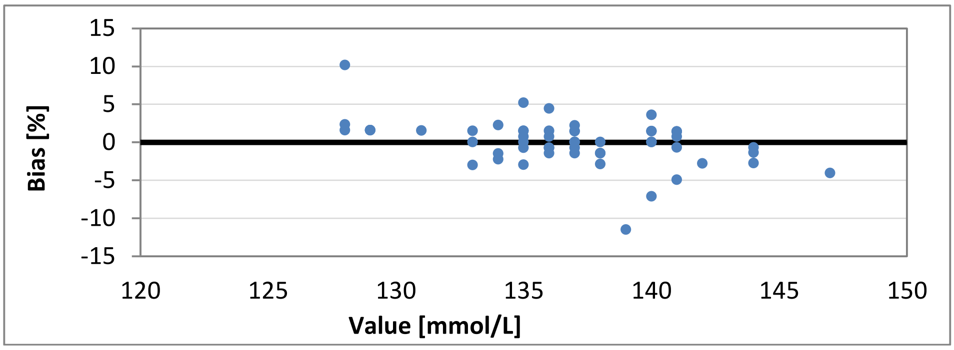


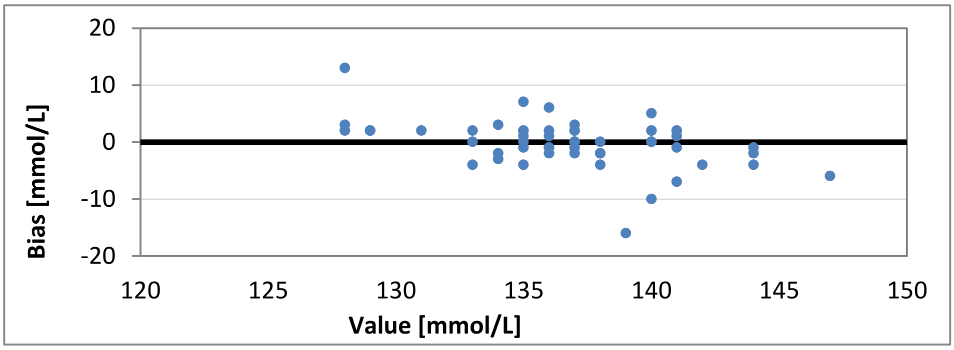
Sodium (n= 55)



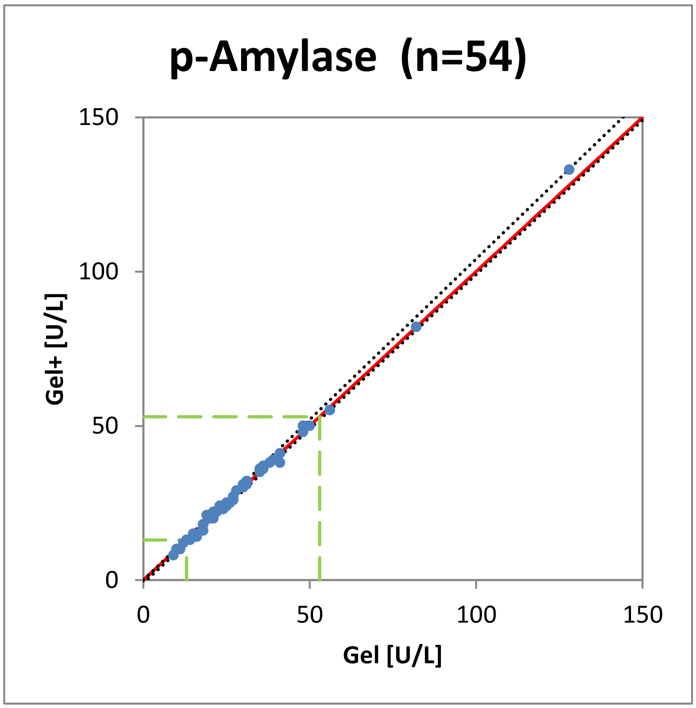
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.3333
95 % CI	0.8462
Axis	0.0000
95 % CI	21.2308
95 % CI	-45.6667

bias at relevant points		
	mmol/L	bias
Average	136.6	0.0%
upper level	136	0.0%
lower level	145	0.0%
acceptable bias		3.0%



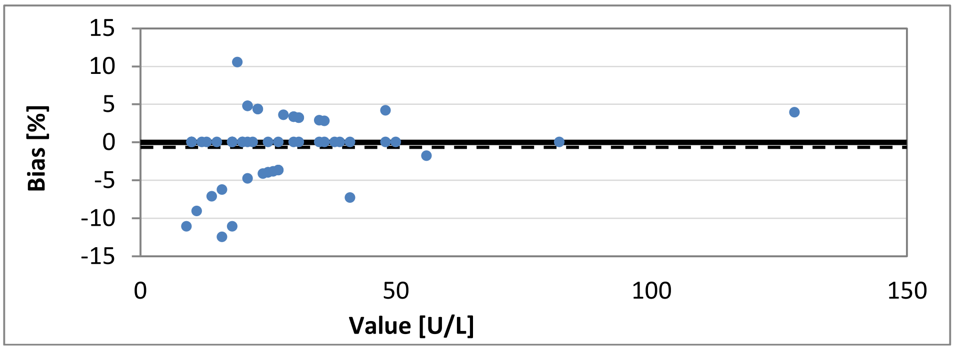


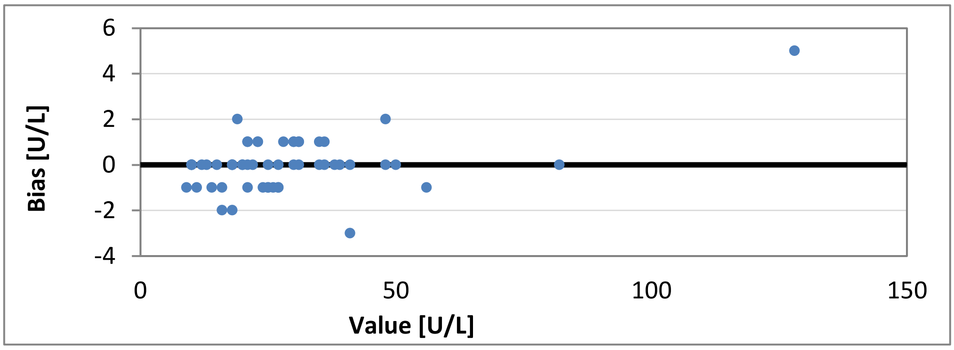
p-Amylase (n= 54)



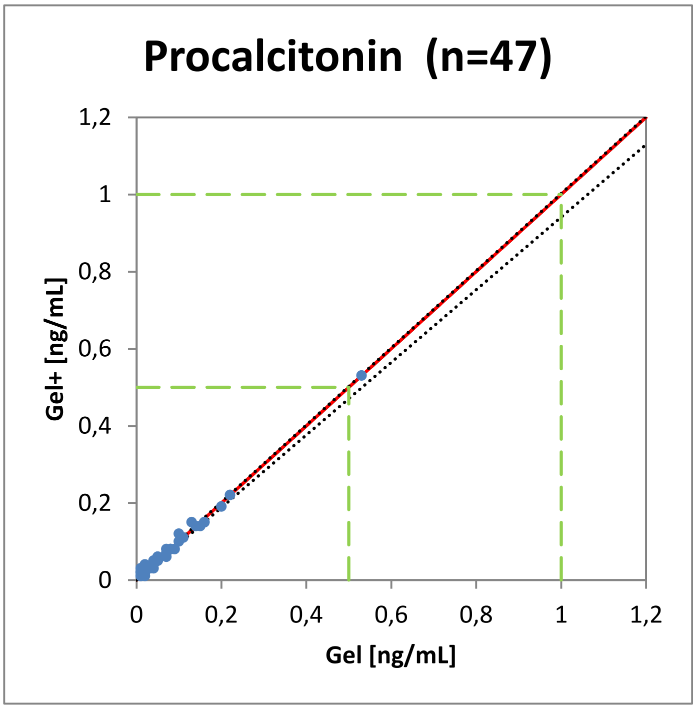
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0408
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	-0.9592

bias at relevant points		
	U/L	bias
Average	28.7	0.0%
upper level	13	0.0%
lower level	53	0.0%
acceptable bias		7.0%



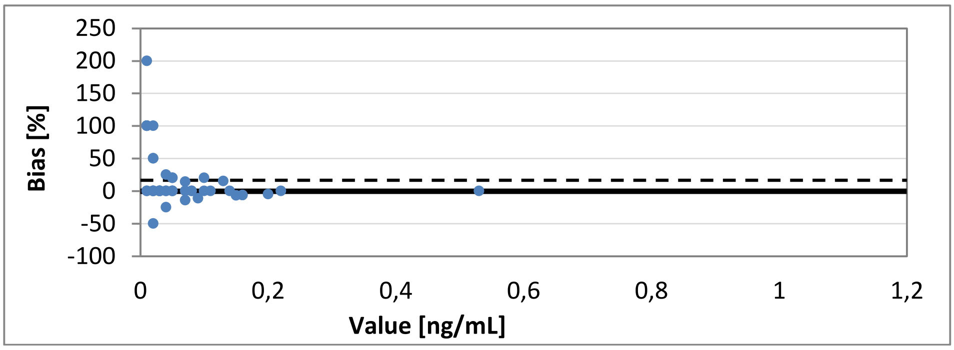


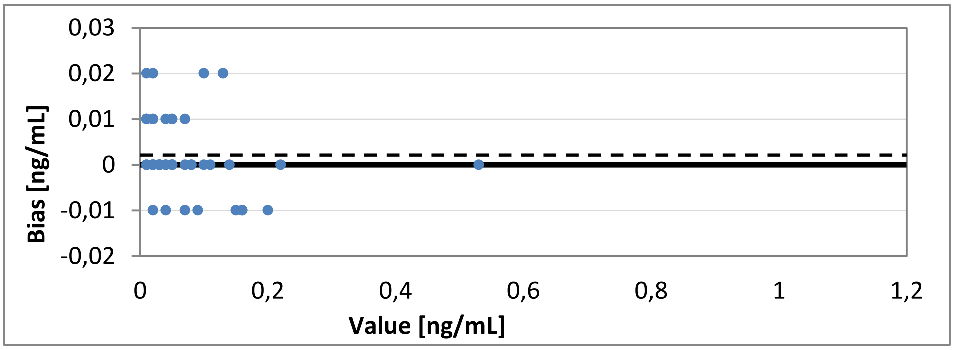
Procalcitonin (n= 47)



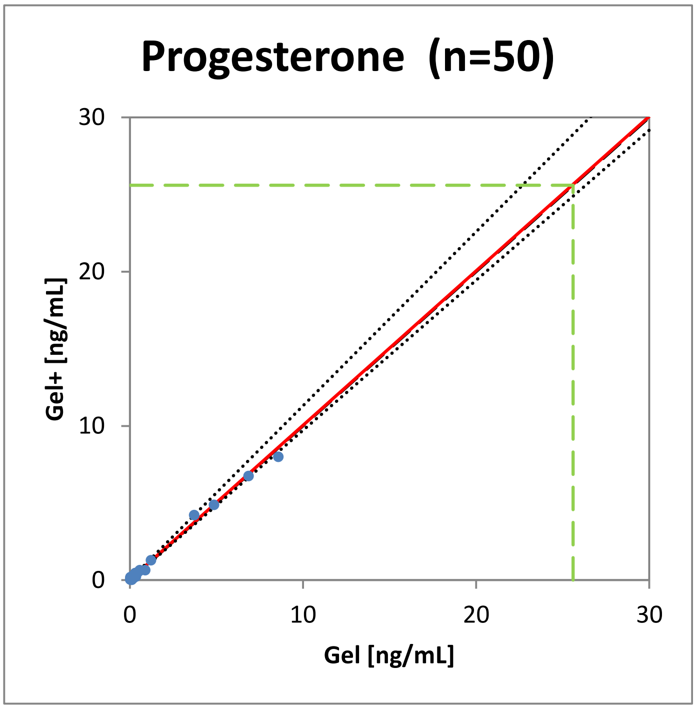
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0000
95 % CI	0.9412
Axis	0.0000
95 % CI	0.0029
95 % CI	0.0000

bias at relevant points		
	ng/mL	bias
Average	0.1	0.0%
upper level	0.5	0.0%
lower level	1	0.0%
acceptable bias		18.0%



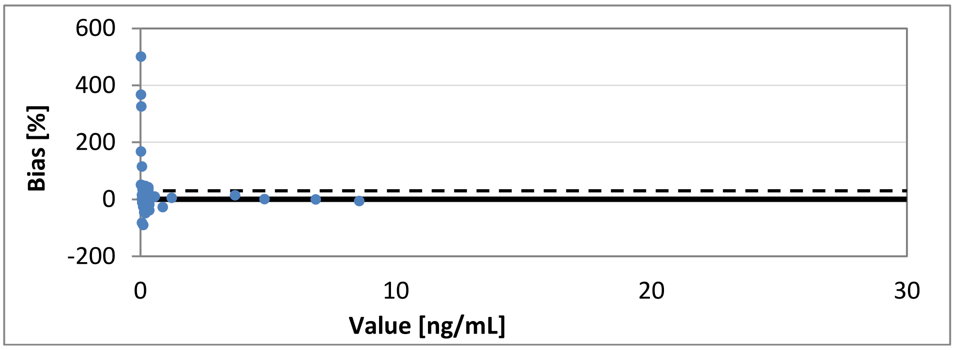


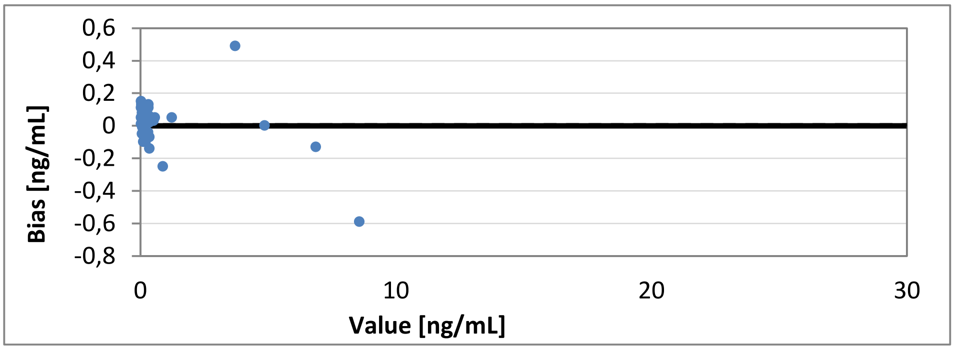
Progesterone (n= 50)



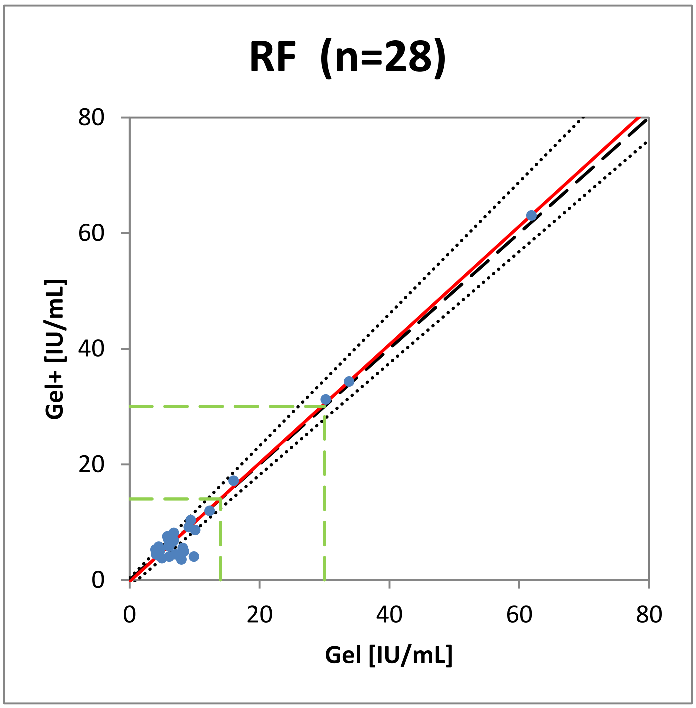
Passing-Bablok Regression	
Slope	1.0018
95 % CI	1.1276
95 % CI	0.9730
Axis	0.0197
95 % CI	0.0330
95 % CI	-0.0080

bias at relevant points		
	ng/mL	bias
Average	0.7	3.1%
upper level	0.28	7.2%
lower level	25.6	0.3%
acceptable bias		17.0%



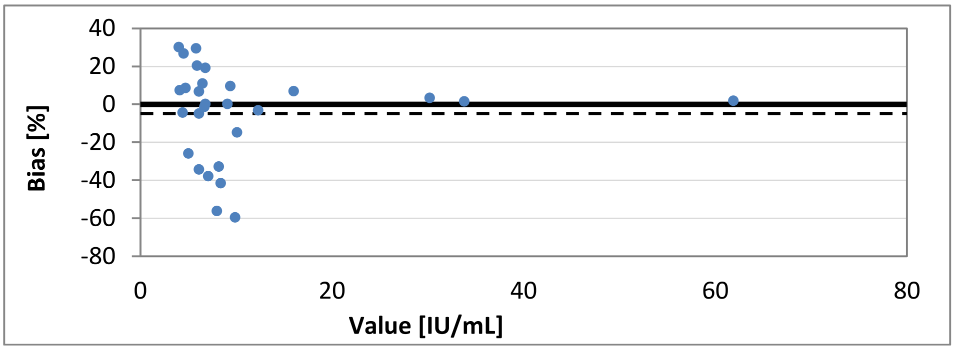


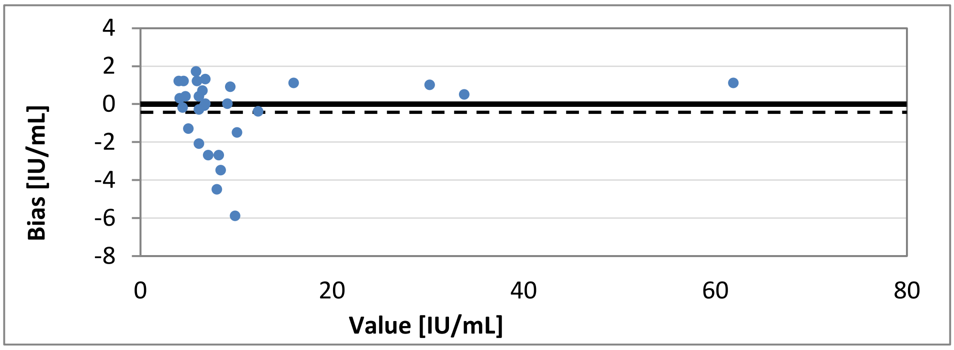
RF (n= 28)



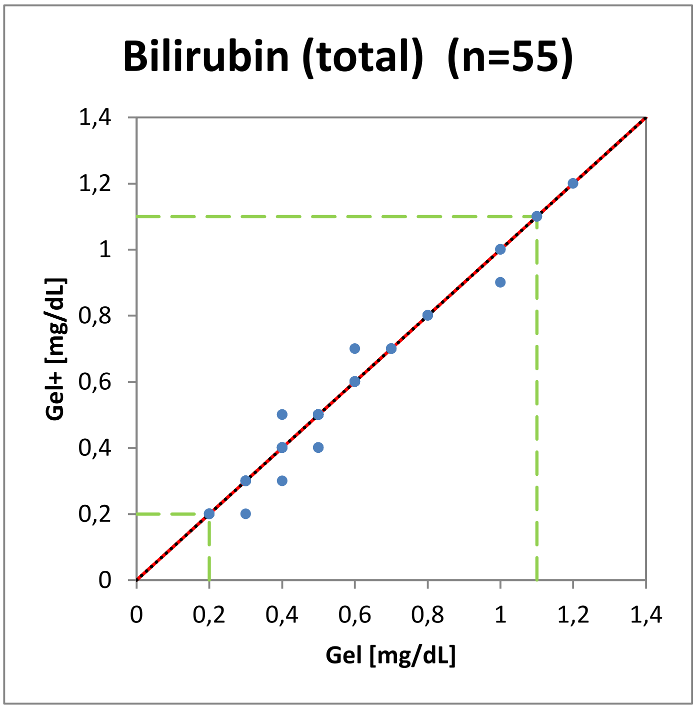
Passing-Bablok Regression	
Slope	1.0237
95 % CI	1.1414
95 % CI	0.9663
Axis	-0.2370
95 % CI	0.3725
95 % CI	-1.1626

bias at relevant points		
	IU/mL	bias
Average	10.8	0.2%
upper level	14	0.7%
lower level	30	1.6%
acceptable bias		13.5%



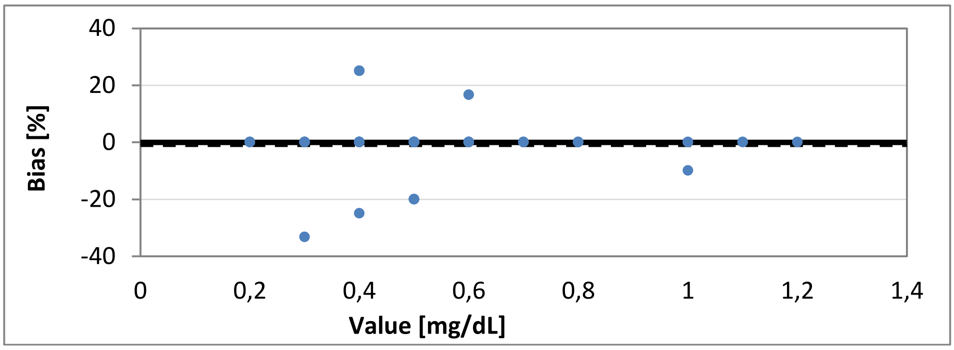


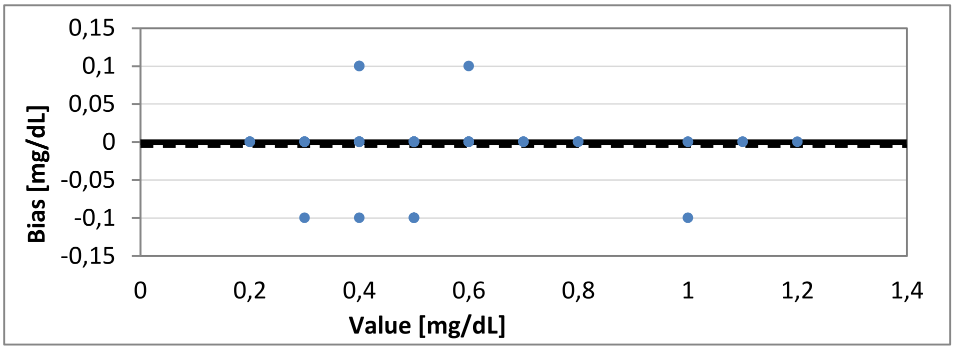
Bilirubin (total) (n= 55)



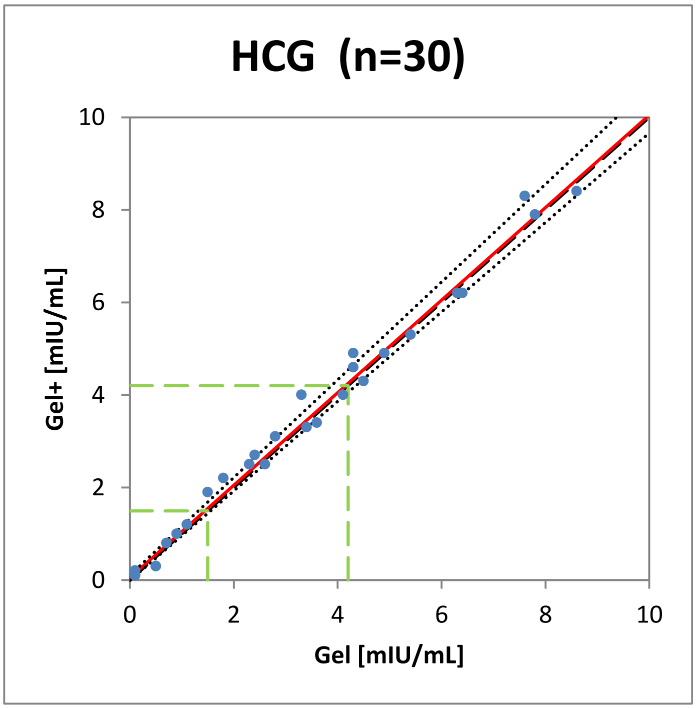
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0000
95 % CI	1.0000
Axis	0.0000
95 % CI	0.0000
95 % CI	0.0000

bias at relevant points		
	mg/dL	bias
Average	0.5	0.0%
upper level	0.2	0.0%
lower level	1.1	0.0%
acceptable bias		22.0%



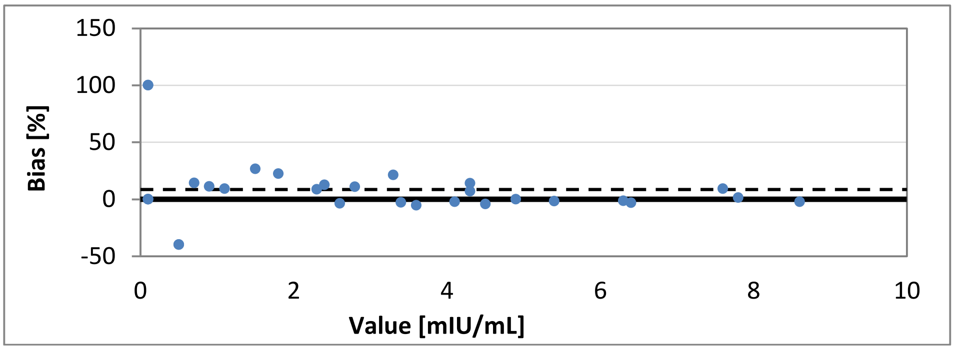


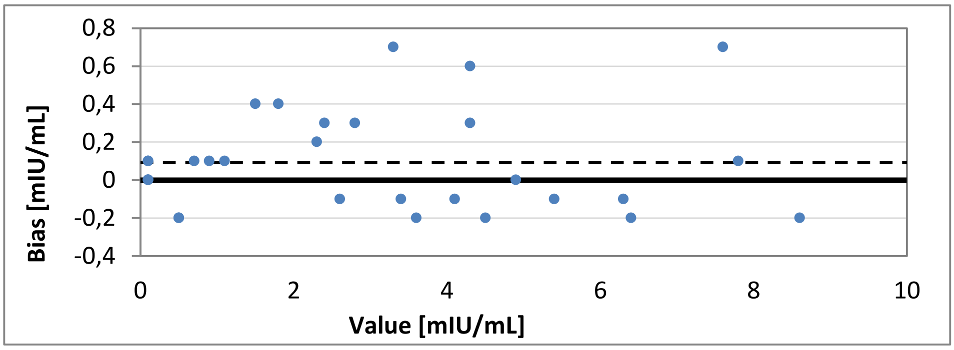
HCG (n= 30)



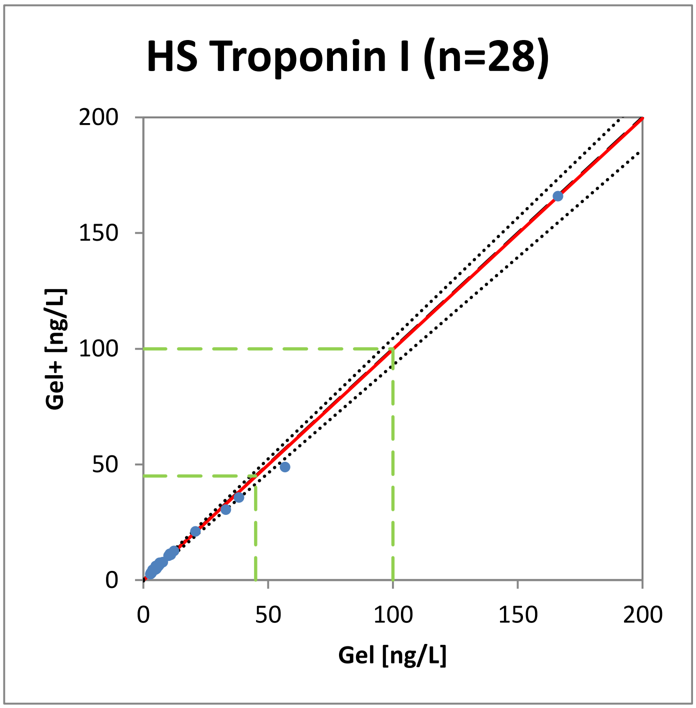
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0556
95 % CI	0.9667
Axis	0.0500
95 % CI	0.1067
95 % CI	-0.0056

bias at relevant points		
	mIU/mL	bias
Average	3.1	1.6%
upper level	1.5	3.3%
lower level	4.2	1.2%
acceptable bias		14.0%



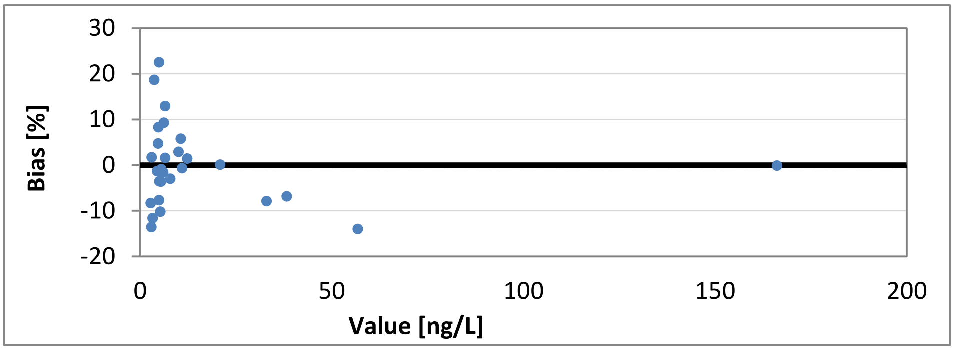


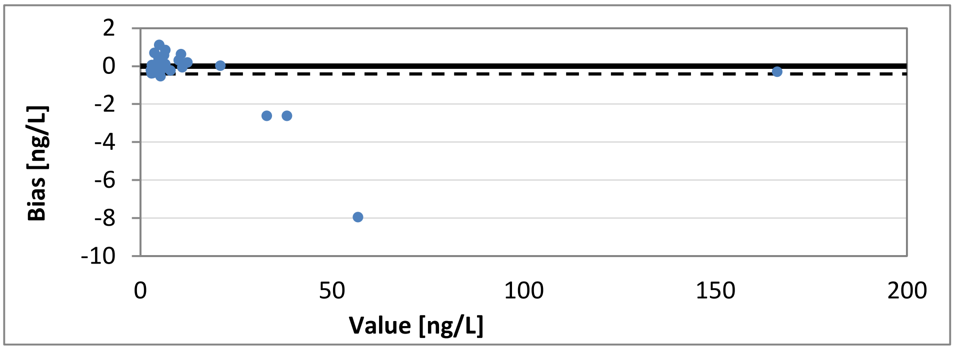
HS Troponin I (n= 28)



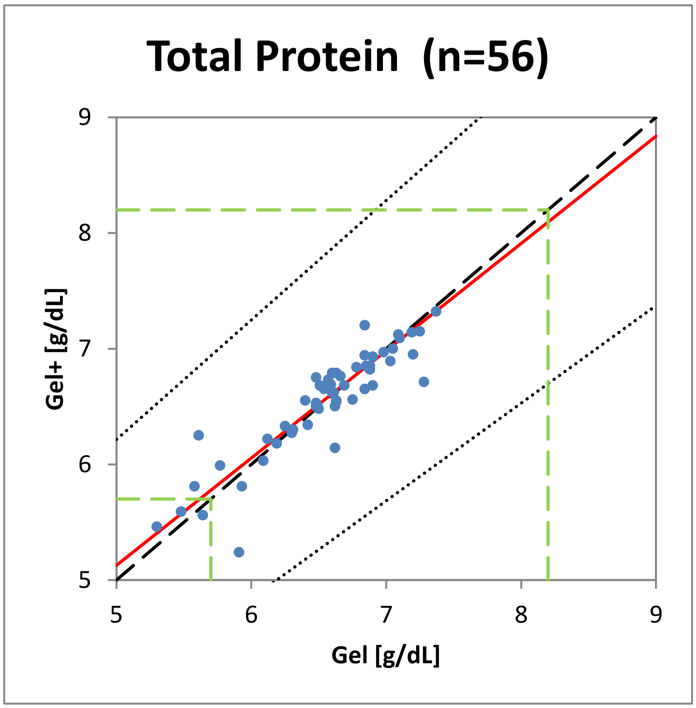
Passing-Bablok Regression	
Slope	0.9982
95 % CI	1.0420
95 % CI	0.9330
Axis	-0.0461
95 % CI	0.3118
95 % CI	-0.3490

bias at relevant points		
	ng/L	bias
Average	16.0	-0.5%
upper level	45	-0.3%
lower level	100	-0.2%
acceptable bias		20.0%



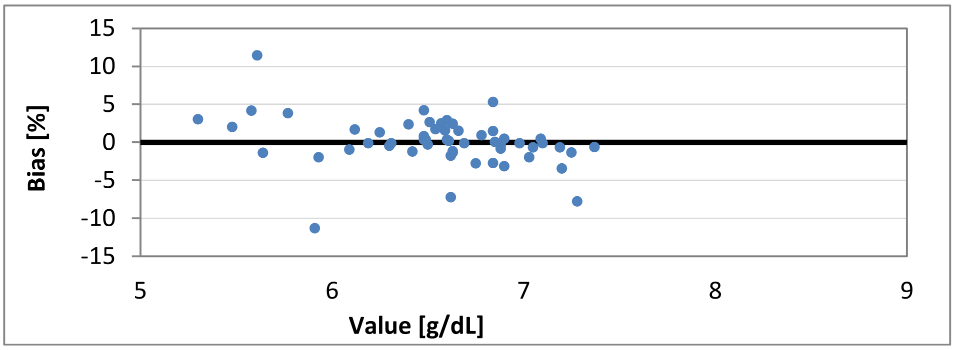


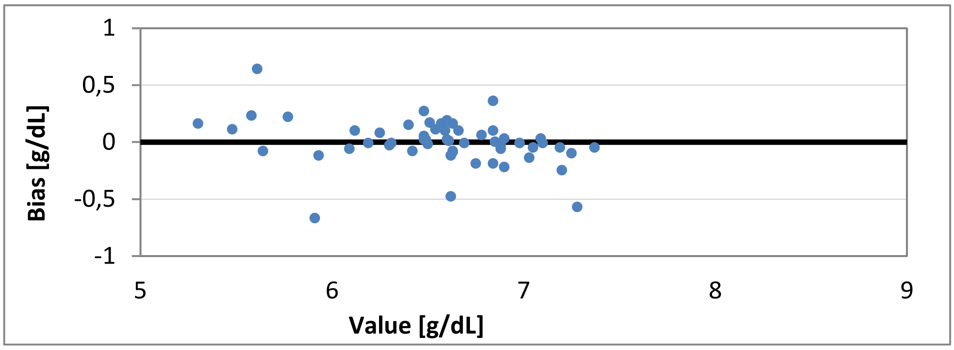
Total Protein (n= 56)



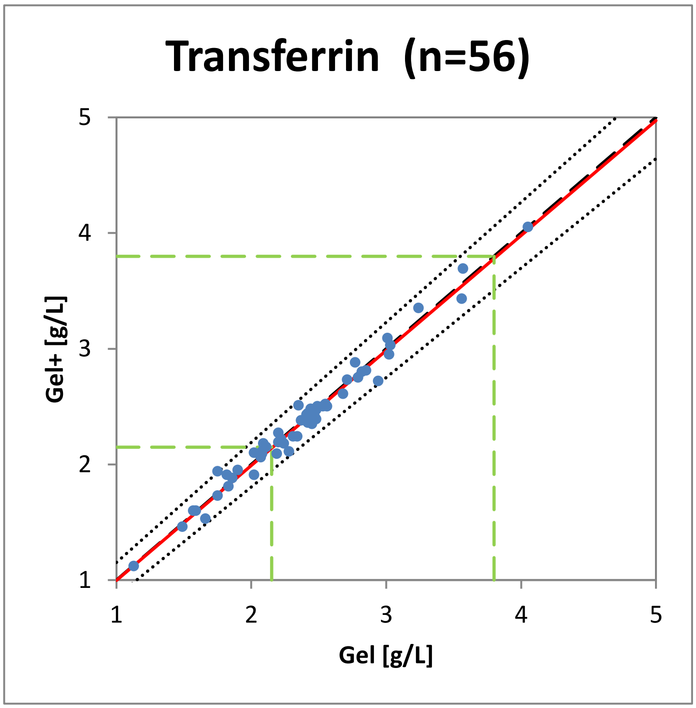
Passing-Bablok Regression	
Slope	0.9275
95 % CI	1.0333
95 % CI	0.8436
Axis	0.4899
95 % CI	1.0493
95 % CI	-0.2183

bias at relevant points		
	g/dL	bias
Average	6.6	0.2%
upper level	5.7	1.3%
lower level	8.2	-1.3%
acceptable bias		6.0%



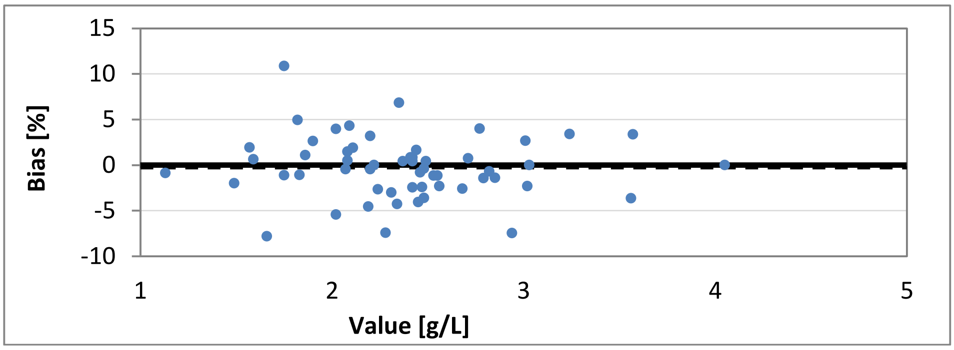


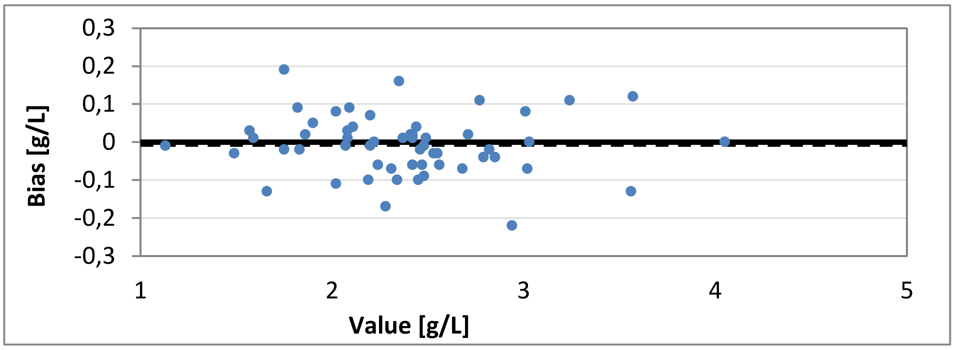
Transferrin (n= 56)



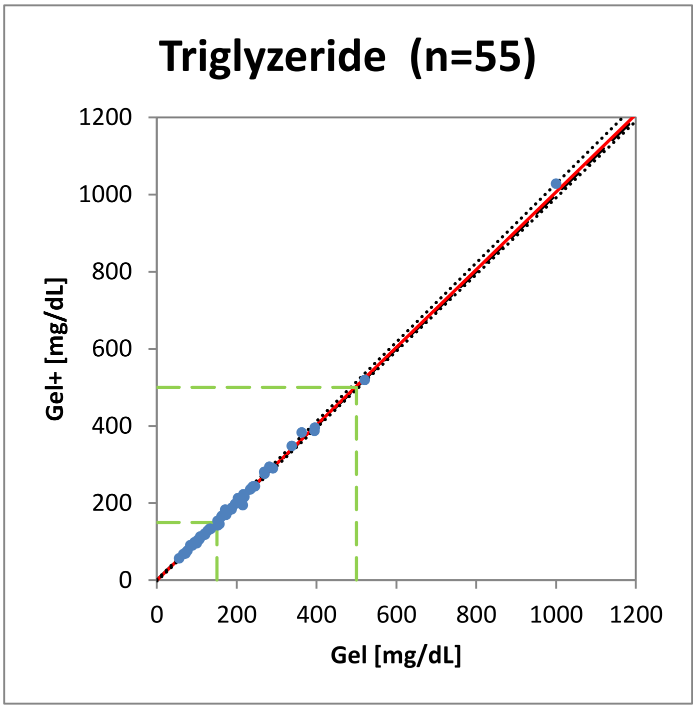
Passing-Bablok Regression	
Slope	0.9937
95 % CI	1.0380
95 % CI	0.9462
Axis	0.0047
95 % CI	0.1138
95 % CI	-0.0876

bias at relevant points		
	g/L	bias
Average	2.4	-0.4%
upper level	2.15	-0.4%
lower level	3.8	-0.5%
acceptable bias		8.0%



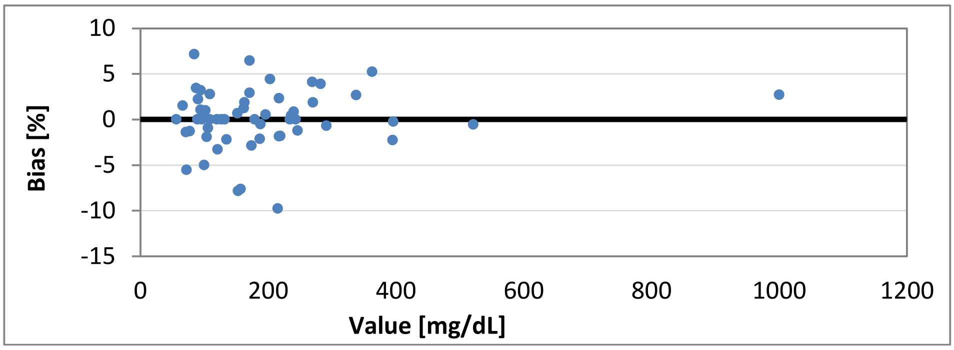


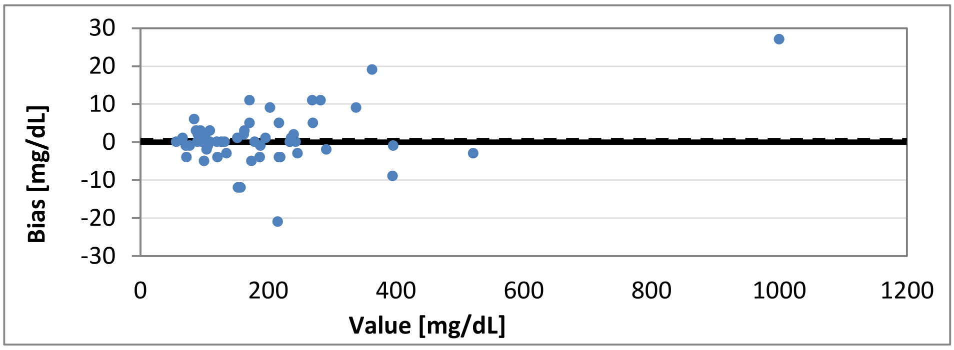
Triglyzeride (n= 55)



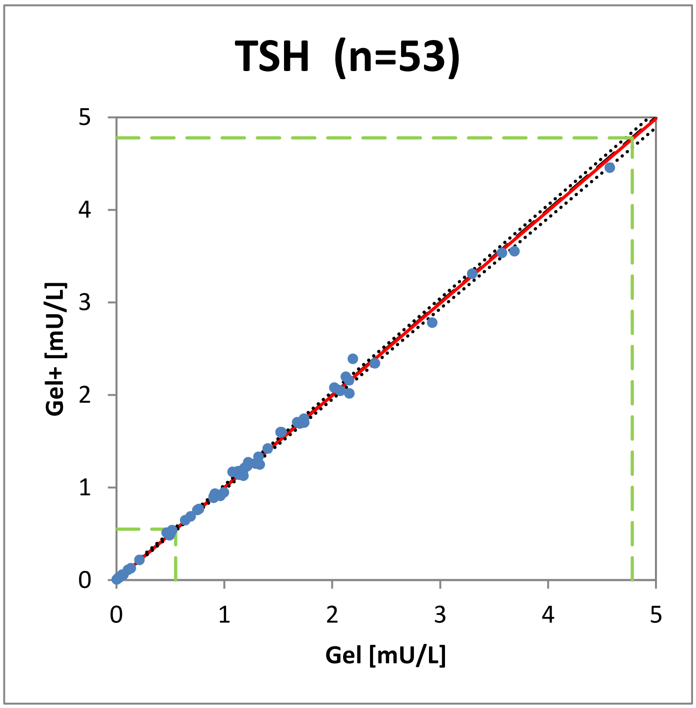
Passing-Bablok Regression	
Slope	1.0068
95 % CI	1.0272
95 % CI	0.9946
Axis	-0.7415
95 % CI	0.9676
95 % CI	-3.2628

bias at relevant points		
	mg/dL	bias
Average	194.7	0.3%
upper level	150	0.2%
lower level	500	0.5%
acceptable bias		9.0%



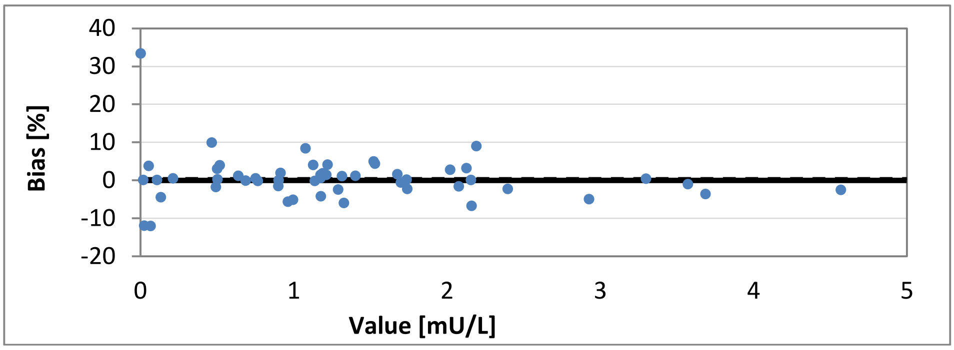


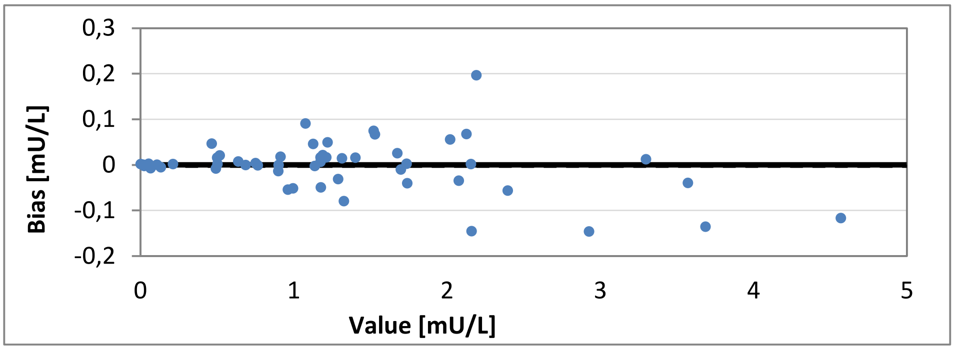
TSH (n= 53)



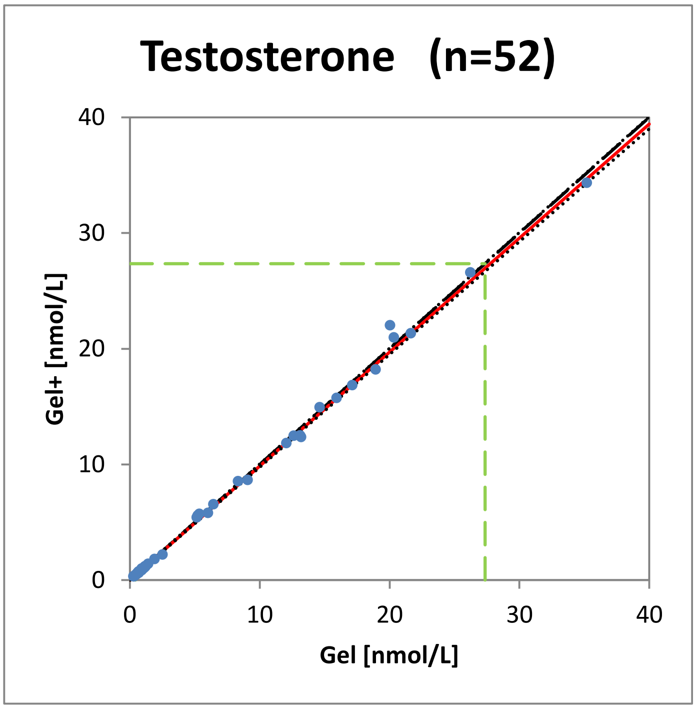
Passing-Bablok Regression	
Slope	0.9971
95 % CI	1.0086
95 % CI	0.9787
Axis	0.0016
95 % CI	0.0190
95 % CI	-0.0034

bias at relevant points		
	mU/L	bias
Average	1.3	-0.2%
upper level	0.55	0.0%
lower level	4.78	-0.3%
acceptable bias		13.5%



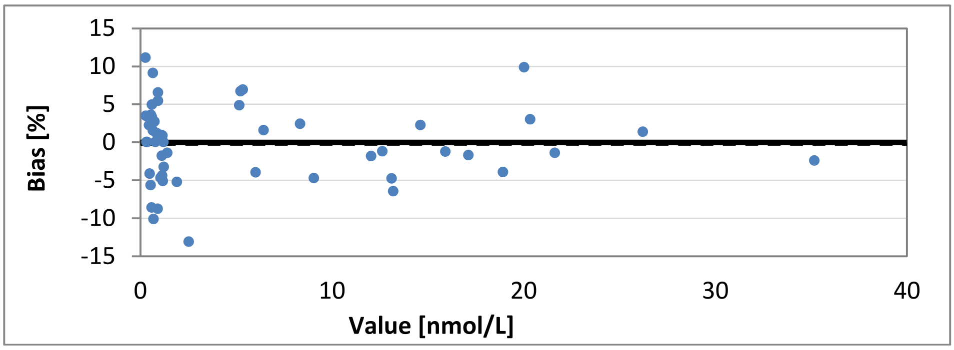


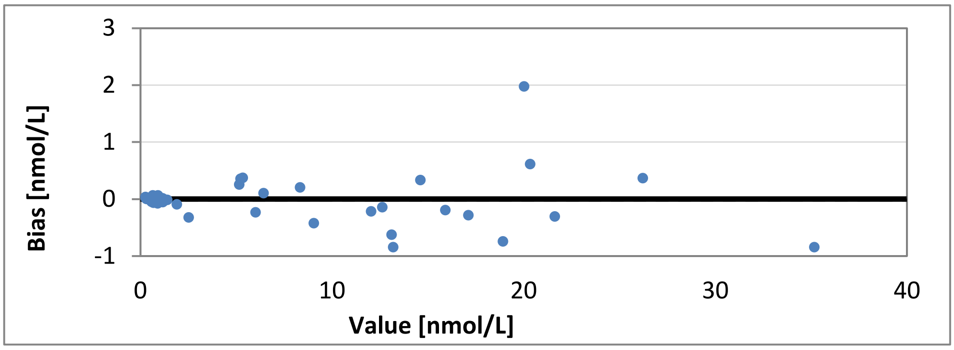
Testosterone (n= 52)



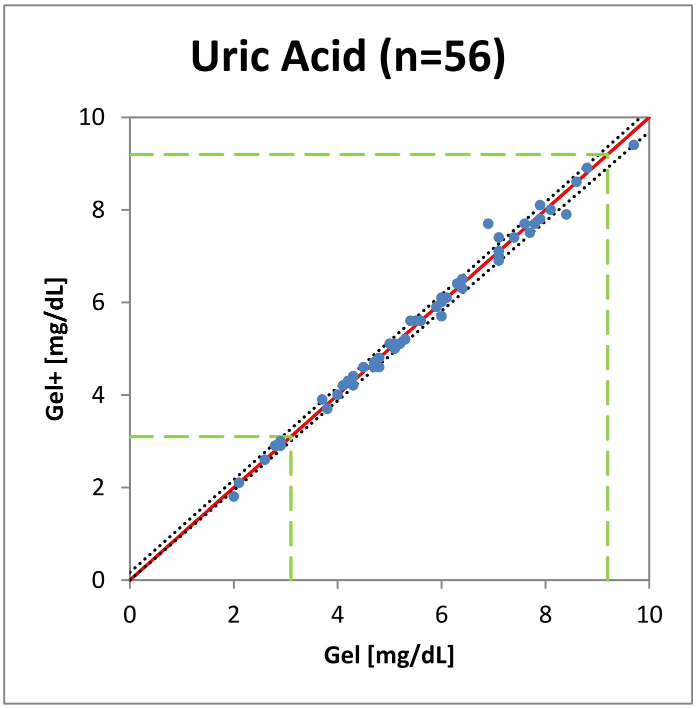
Passing-Bablok Regression	
Slope	0.9854
95 % CI	1.0005
95 % CI	0.9750
Axis	0.0154
95 % CI	0.0304
95 % CI	-0.0003

bias at relevant points		
	nmol/L	bias
Average	6.0	-1.2%
upper level	0.42	2.2%
lower level	27.35	-1.4%
acceptable bias		20.5%



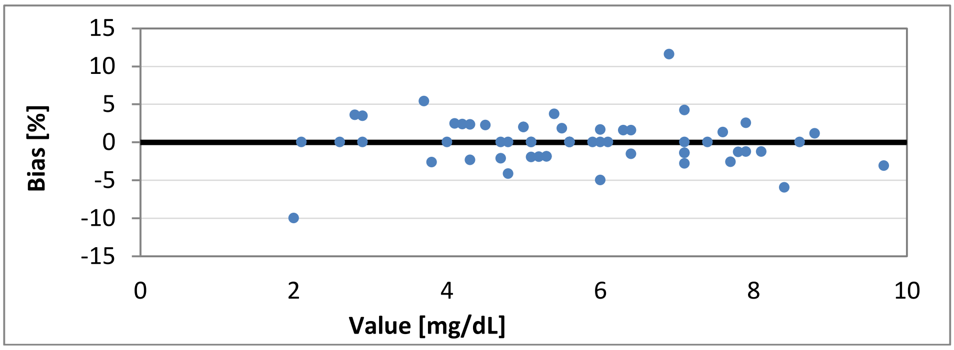


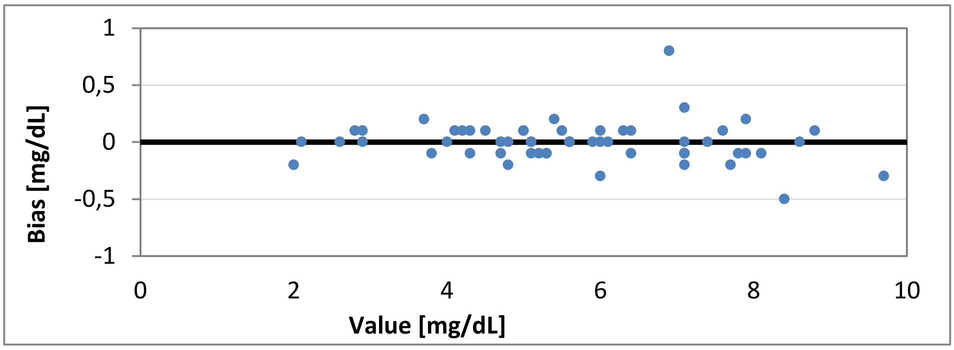
Uric Acid (n= 56)



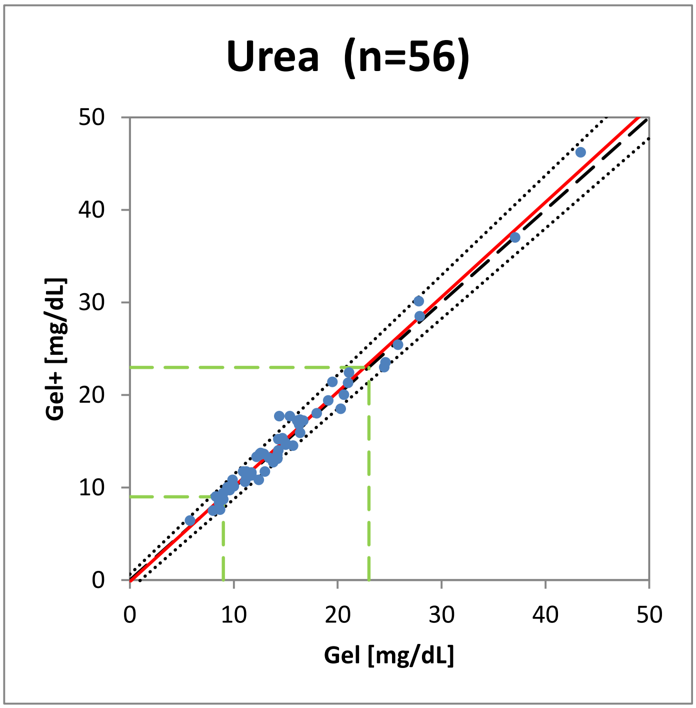
Passing-Bablok Regression	
Slope	1.0000
95 % CI	1.0000
95 % CI	0.9688
Axis	0.0000
95 % CI	0.1672
95 % CI	0.0000

bias at relevant points		
	mg/dL	bias
Average	5.7	0.0%
upper level	3.1	0.0%
lower level	9.2	0.0%
acceptable bias		7.0%



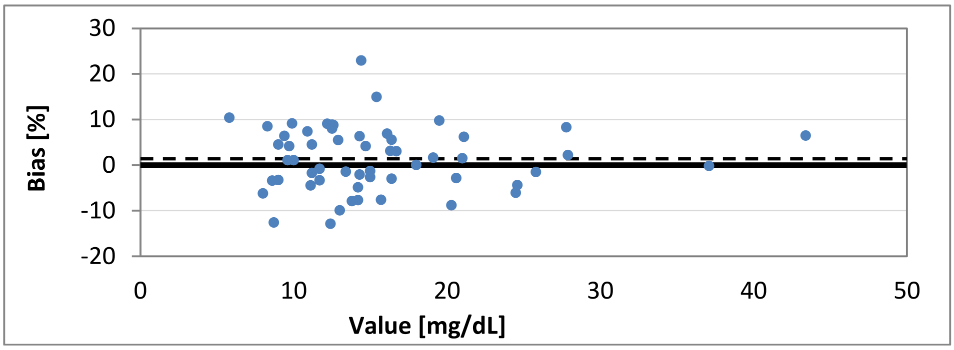


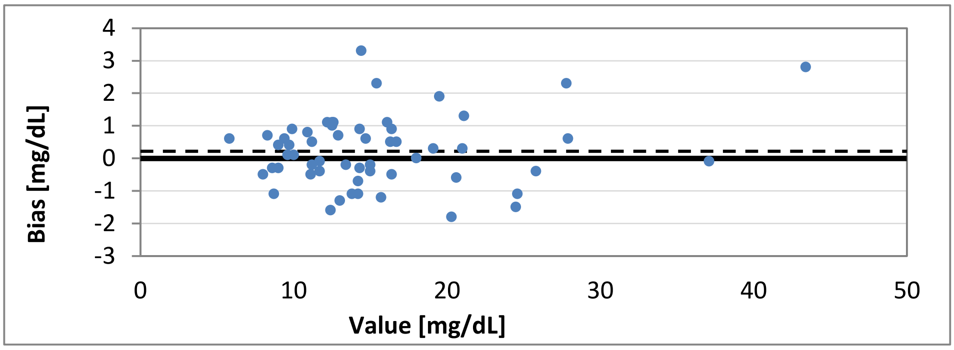
Urea (n= 56)



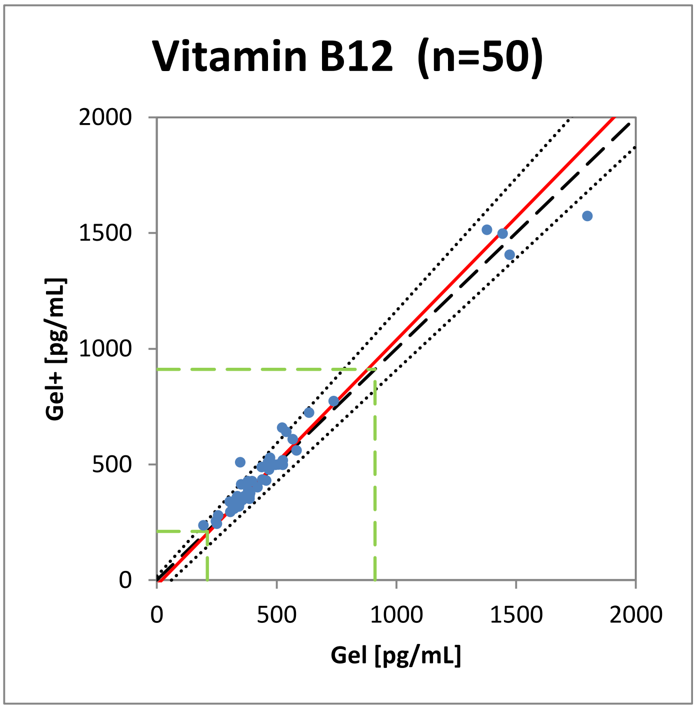
Passing-Bablok Regression	
Slope	1.0247
95 % CI	1.0769
95 % CI	0.9744
Axis	-0.1593
95 % CI	0.6397
95 % CI	-0.9769

bias at relevant points		
	mg/dL	bias
Average	15.6	1.4%
upper level	9	0.7%
lower level	23	1.8%
acceptable bias		10.5%



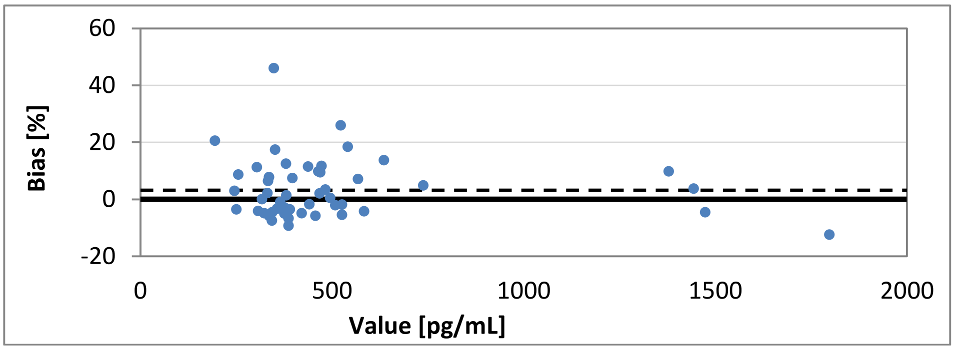


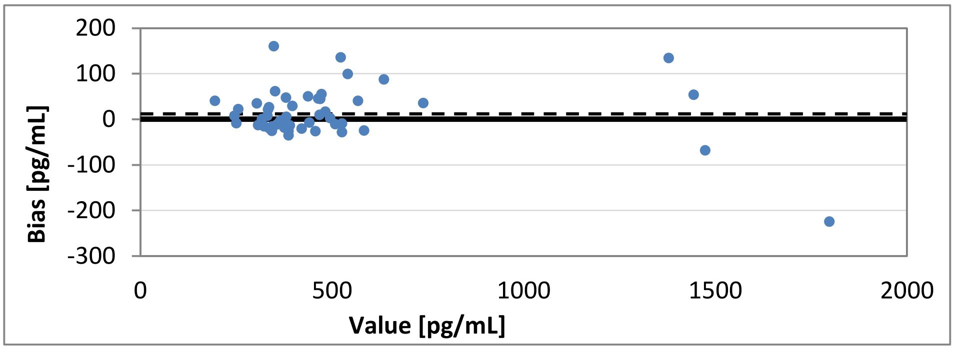
Vitamin B12 (n= 50)



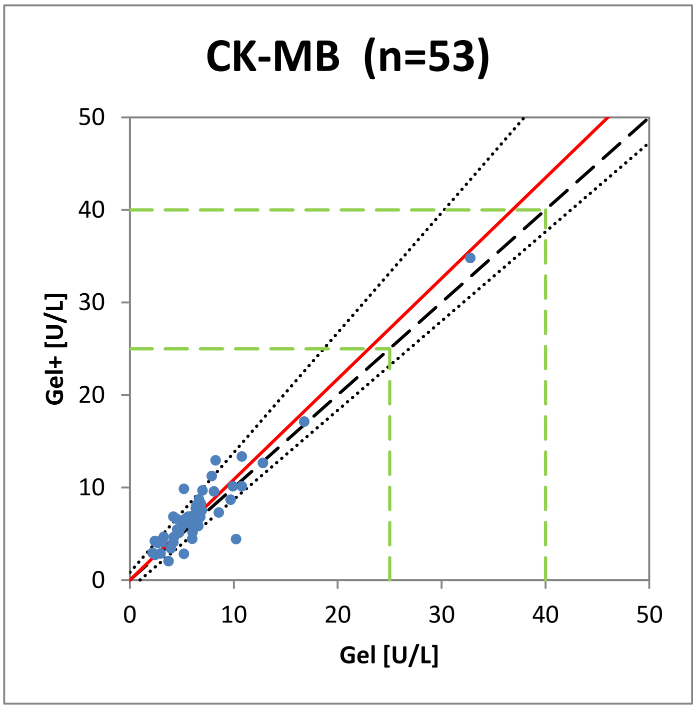
Passing-Bablok Regression	
Slope	1.0592
95 % CI	1.1471
95 % CI	0.9663
Axis	-21.3165
95 % CI	16.5674
95 % CI	-58.9853

bias at relevant points		
	pg/mL	bias
Average	505.1	1.7%
upper level	211	-4.2%
lower level	911	3.6%
acceptable bias		25.0%





CK-MB (n= 53)



Passing-Bablok Regression	
Slope	1.0859
95 % CI	1.2946
95 % CI	0.9640
Axis	0.0257
95 % CI	0.8467
95 % CI	-0.9135

bias at relevant points		
	U/L	bias
Average	7.0	9.0%
upper level	25	8.7%
lower level	40	8.7%
acceptable bias		24.1%